

HPLC & LC-MS/MS

IVD Complete Kits



Product Catalogue I
2020/2021



Dear customers,

We are proud to present our new RECIPE product catalogues “IVD Complete Kits” and “Quality Assurance” reflecting our enlarged range of HPLC and LC-MS/MS kit solutions. As one of the leading CE-IVD providers in this area we are committed to meet the needs in your clinical laboratory. Apart from our established products we would like to focus on our TDM Kit System, which is available in drug-specific and rapidly expanding Add-on-Sets.

Today RECIPE is present in more than 80 countries with certified distributors as well as direct sales. A growing team of currently 70 employees including R&D Professionals, Application Specialists, Quality and Product Managers is dedicated to provide and satisfy your diagnostic needs.

Since more than 30 years our premium quality products are designed, developed and manufactured in our facilities in Munich. We regularly participate in National and European proficiency schemes. All processes are controlled and certified according to ISO 13485.

A close relationship with university and research laboratories is a key pillar for developing market-specific HPLC and LC-MS/MS applications.

Our vision to continuously develop and improve in-vitro diagnostic products and services provided to our valued customers shall ultimately ensure better medical treatment, quality of life and healthy aging of patients.

We thank you for the ongoing business and we look forward to building a successful partnership.

A handwritten signature in blue ink, appearing to read 'G. Wolfram'. The signature is fluid and cursive.

Dr. Gernot Wolfram
CEO

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ClinMass® TDM Kit System

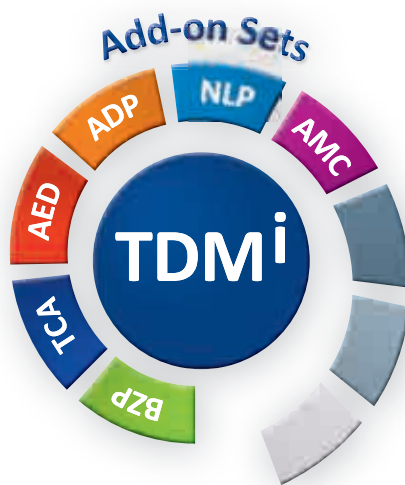
The ClinMass® TDM Kit System is based on our complete kit philosophy and allows to enlarge the spectrum of analytical parameters by simple kit combination. A universal chromatography kit (ClinMass® Platform) can be used for the analysis of several different TDM parameters. For this purpose appropriate ClinMass® Add-on Sets (e.g. for Benzodiazepines, TCAs, AEDs, etc.) are provided.



The ClinMass® TDM Kit System is also available for on-line SPE analysis









Direct Injection:

Internal Standard is added to real serum or plasma sample, calibrator or control by just one simple pipetting step of the autosampler followed by direct injection of the individual samples into the chromatographic system. Subsequently, the analytes are separated and determined by on-line analysis.



The ClinMass® TDM Kit System is based on a universal TDM Platform (order no. MS9000), which can be used for several different TDM analytes. Select your analyte panel by choosing the suitable ClinMass® Add-On Sets!

Currently, the following ClinMass® Add-on Sets are available

| | |
|------------------------------------------------------------------------------------|---------------------------|
|  | Antidepressants |
|  | Antiepileptic Drugs |
|  | Antimycotics |
|  | Benzodiazepines |
|  | Mycophenolic Acid |
|  | Neuroleptics |
|  | Tricyclic Antidepressants |
|  | Immunosuppressants |

The benefits of the ClinMass® TDM Kit System

- ▶ Determination of currently 156 different analytes
 - using one TDM Platform (i.e. identical sample preparation and mobile phases) and
 - one analytical column
- ▶ Simple one-step sample preparation for a quick sample processing



1. HPLC Complete Kits

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ClinRep® HPLC Complete Kits are designed for diagnosis and Therapeutic Drug Monitoring (TDM) in clinical, toxicological and forensic laboratories. ClinTox® HPLC Complete Kits are designed for Human Biomonitoring (HBM) in laboratories for occupational medicine.

Our kits can be used with any conventional HPLC system. A complete kit contains all components required for analysis, such as buffers, reagents for sample preparation, standards and a matrix calibrator. Start accessories such as guard-, SPE-, and analytical columns, matrix controls and further accessories are additionally available.



CDT in Serum

CDT (Carbohydrate Deficient Transferrin) is the most specific parameter for chronic alcohol abuse. The ClinRep® HPLC Complete Kit for CDT provides a unique chromatographical resolution compared to other commercially available test kits. The analytical method correlates with the candidate reference method of the IFCC-CDT-WG* and ensures a reliable separation of all relevant transferrin isoforms (a-, mono-, di-, ..., hexasialotransferrin). This applies in particular for disialotransferrin, which is the defined analyte by the IFCC-CDT-WG*. Alternatively to this method with manual sample preparation, ClinRep® Complete Kits for on-line analysis and automated on-line analysis via 96-well plates are available.

* Working group of the IFCC for the international standardisation of CDT measurement.

- Unique chromatographical resolution
- Quantification of all relevant transferrin isoforms (incl. hexasialotransferrin)
- Baseline-separation of disialotransferrin



Test Data

LOD: 0.1 %*

LLOQ: 0.3 %*

Intraassay precision: 4.2 %

Interassay precision: 4.3 %

* depending on the amount of total transferrin and on detector sensitivity

HPLC Parameters

Pump: Quarternary gradient pump,
flow rates: 1.2, 2.0 ml/min

Injection volume: 400 - 500 µl

Injection interval: 20 min

UV/VIS-Detector: 460 nm

HPLC-Thermostat: 40 °C

Sample Preparation

Stabilisation/Precipitation:

| | | |
|--------------|-----------------------------|-------------------------------------|
| 150 µl serum | 30 µl Stabilising Reagent S | 10 µl mixture of Precipitants P1+P2 |
|--------------|-----------------------------|-------------------------------------|

1. incubate (30 min, 4 °C)
2. centrifuge

Dilution:

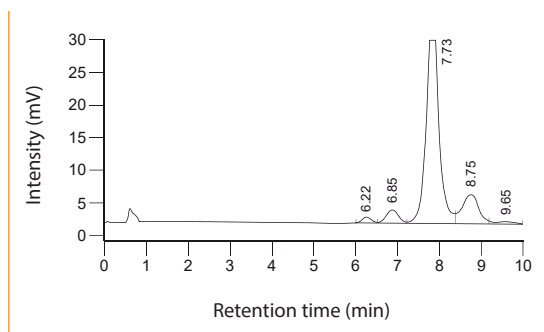
| | |
|--------------------|----------------------------|
| 100 µl supernatant | 1.0 ml Diluting Solution D |
|--------------------|----------------------------|

HPLC Analysis:

| |
|---------------------|
| Inject 400 - 500 µl |
|---------------------|

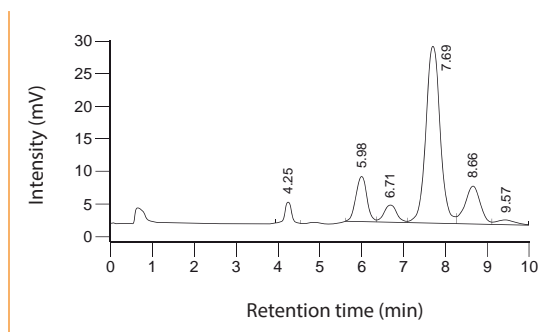
1.1.1. Alcoholism

Native sample, normal range



Disialotransferrin: 6.22 min, Trisialotransferrin: 6.85 min,
Tetrasialotransferrin: 7.73 min, Pentasialotransferrin: 8.75 min,
Hexasialotransferrin: 9.65 min

Native sample, pathological range



Asialotransferrin: 4.25 min, Disialotransferrin: 5.98 min,
Trisialotransferrin: 6.71 min, Tetrasialotransferrin: 7.69 min,
Pentasialotransferrin: 8.66 min, Hexasialotransferrin: 9.57 min

Ordering Information

| Order No. | Description | Quantity |
|------------------------------------------|---------------------------------------------------------------------------------|--------------------------|
| 21000 | ClinRep® Complete Kit for CDT in Serum for 100 assays | 1 pce. |
| Kit Components (order no. 21000): | | |
| 21007 | Mobile Phase A | 3 x 21007 (3 x 2000 ml) |
| 21008 | Mobile Phase B | 2000 ml |
| 21009 | Mobile Phase C | 2000 ml |
| 21020 | Sample Preparation Vials | 2 x 21020 (2 x 100 pcs.) |
| 21021 | Stabilising Reagent S | 3 ml |
| 21022 | Precipitant P1 | 1 ml |
| 21023 | Precipitant P2 | 2 ml |
| 21024 | Diluting Solution D | 100 ml |
| | Manual | 1 pce. |
| | Quick Reference | 1 pce. |
| Optional Components: | | |
| 21013 | Serum Calibrator Set, lyophil. (Level 1 - 2) | 2 x 1 x 1 ml |
| 21014 | Test Solution | 15 ml |
| Start Accessories: | | |
| 21030 | Analytical Column with test chromatogram | 1 pce. |
| 21032 | Cartridge incl. 1 precolumn | 1 pce. |
| Refill Service: | | |
| 21031 | Analytical Column with test chromatogram (original column needs to be returned) | 1 pce. |
| Accessories: | | |
| 21033 | Precolumns | 5 pcs. |
| FK5810 | PEEK tubing (connection of prefilter and column) | 1 pce. |
| FW3000 | Fixed-Wavelength-VIS-Detector (460 nm), complete | 1 pce. |
| RC2002 | Sodium-Hypochlorite-Solution (5 %) | 12 ml |
| ClinChek® Controls: | | |
| 21080 | Serum Control, lyophil., Level I | 10 x 1 ml |
| 21081 | Serum Control, lyophil., Level II | 10 x 1 ml |
| 21082 | Serum Control, lyophil., Level I, II | 2 x 5 x 1 ml |

1.1.1. Alcoholism

CDT in Serum

► on-line Analysis

This ClinRep® Complete Kit is designed for the fast analysis of CDT with on-line SPE. It features an injection interval of 9.5 min only and provides a unique chromatographical resolution compared to other commercially available test kits. Analogously to our kit with manual sample preparation, the on-line procedure correlates with the candidate reference method of the IFCC-CDT-WG*. Prior to the sample injection, a simple dilution step is required ("sample pretreatment", see below). Alternatively the dilution can be performed automated via 96-well plates. For this purpose an additional ClinRep® Complete Kit is available.

* Working group of the IFCC for the international standardisation of CDT measurement.

- One step sample pretreatment
- Fast analysis: injection interval of 9.5 min
- Unique chromatographical quality



Test Data

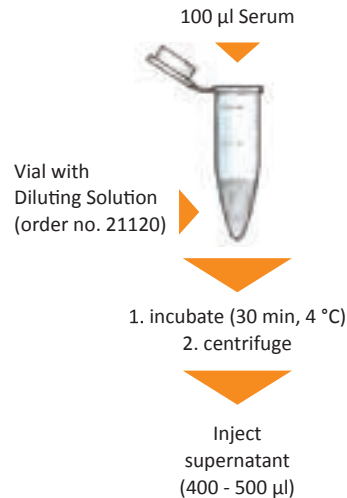
| | |
|-----------------------|--------|
| LOD: | 0.1 %* |
| LLOQ: | 0.3 %* |
| Intraassay precision: | 4.5 % |
| Interassay precision: | 3.9 % |

* depending on the amount of total transferrin and on detector sensitivity

HPLC Parameters

| | |
|---------------------|------------------------------------------------|
| Pump 1: | binary gradient pump, flow rate: 1.4 ml/min |
| Pump 2: | isocratic pump, flow rate: 0.4 ml/min |
| Injection volume: | 400 - 500 µl |
| Injection interval: | 9.5 min |
| UV/VIS-Detector: | 460 nm |
| HPLC-Thermostat: | 40 °C |

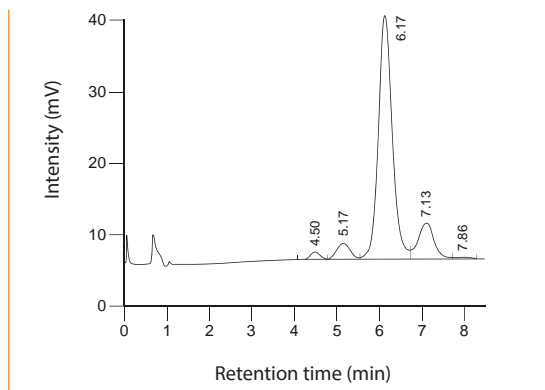
Sample Pretreatment



**One step
sample pretreatment!**

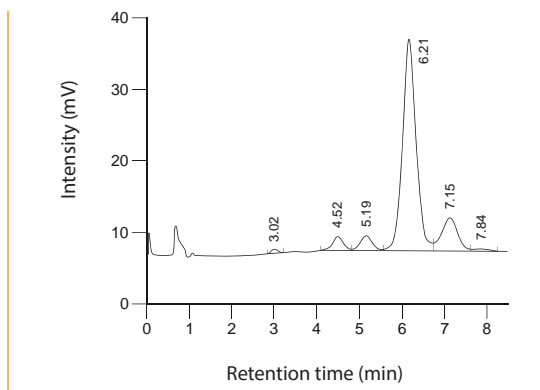
1.1.1. Alcoholism

Native sample, normal range



Disialotransferrin: 4.50 min, Trisialotransferrin: 5.17 min, Tetrasialotransferrin: 6.17 min, Pentasialotransferrin: 7.13 min, Hexasialotransferrin: 7.86 min

Native sample, pathological range



Asialotransferrin: 3.02 min, Disialotransferrin: 4.52 min, Trisialotransferrin: 5.19 min, Tetrasialotransferrin: 6.21 min, Pentasialotransferrin: 7.15 min, Hexasialotransferrin: 7.84 min

Ordering Information

| Order No. | Description | Quantity |
|------------------------------------------|---------------------------------------------------------------------------------|-------------------------|
| 21100 | ClinRep® Complete Kit for CDT in Serum for 300 assays | 1 pce. |
| Kit Components (order no. 21100): | | |
| 21007 | Mobile Phase A | 3 x 21007 (3 x 2000 ml) |
| 21008 | Mobile Phase B | 2000 ml |
| 21009 | Mobile Phase C | 2 x 21009 (2 x 2000 ml) |
| 21020 | Vials for Sample Pretreatment with Diluting Solution | 6 x 21120 (6 x 50 pcs.) |
| | Manual | 1 pce. |
| | Quick Reference | 1 pce. |
| Optional Components: | | |
| 21013 | Serum Calibrator Set, lyophil. (Level 1 - 2) | 2 x 1 x 1 ml |
| 21014 | Test Solution | 15 ml |
| Start Accessories: | | |
| 21030 | Analytical Column with test chromatogram | 1 pce. |
| 21032 | Cartridge incl. 1 precolumn | 1 pce. |
| FK5820 | Stainless steel prefilter holder incl. 1 prefilter | 1 pce. |
| FK7400 | Inline-Filter (stainless steel sieve, free of dead volume) | 1 pce. |
| Refill Service: | | |
| 21031 | Analytical Column with test chromatogram (original column needs to be returned) | 1 pce. |
| Accessories: | | |
| 21033 | Precolumns | 5 pcs. |
| FK1102 | Switching valve, Sykam (6-port/3-channel incl. electr. drive, PEEK) | 1 pce. |
| FK5810 | PEEK tubing (connection of prefilter and column) | 1 pce. |
| FK5821 | Replacement filter for stainless steel prefilter holder | 10 pcs. |
| FK7340 | Sealings and sieves for order no. FK7400 | 4 pcs. each |
| FW3000 | Fixed-Wavelength-VIS-Detector (460 nm), complete | 1 pce. |
| RC2002 | Sodium-Hypochlorite-Solution (5 %) | 12 ml |
| ClinChek® Controls: | | |
| 21080 | Serum Control, lyophil., Level I | 10 x 1 ml |
| 21081 | Serum Control, lyophil., Level II | 10 x 1 ml |
| 21082 | Serum Control, lyophil., Level I, II | 2 x 5 x 1 ml |

1.1.1. Alcoholism

CDT in Serum

► automated on-line Analysis

This ClinRep® Complete Kit is designed for the fully automated analysis of CDT with liquid handling systems and subsequent on-line SPE. The analytical method correlates with the candidate reference method of the IFCC-CDT-WG* and ensures a reliable separation of all relevant transferrin isoforms (a-, mono-, di-, ..., hexasialo-transferrin). This applies in particular for disialo-transferrin, which is the defined analyte by the IFCC-CDT-WG*. An accurate calculation of the CDT value is ensured by baseline separation.

* Working group of the IFCC for the international standardisation of CDT measurement.

- Fully automated method
- Fast analysis: injection interval of 9.5 min
- Unique chromatographical resolution



Test Data

| | |
|-----------------------|--------|
| LOD: | 0.1 %* |
| LLOQ: | 0.3 %* |
| Intraassay precision: | 2.8 % |
| Interassay precision: | 2.5 % |

* depending on the amount of total transferrin and on detector sensitivity

HPLC Parameters

| | |
|---------------------|------------------------------------------------|
| Pump 1: | binary gradient pump, flow rate: 1.4 ml/min |
| Pump 2: | isocratic pump, flow rate: 0.4 ml/min |
| Injection volume: | 400 µl |
| Injection interval: | 9.5 min |
| UV/VIS-Detector: | 460 nm |
| HPLC-Thermostat: | 40 °C |

Sample Pretreatment (Liquid Handling System)

Dilution:

| | |
|-------------------------------|----------------|
| 500 µl Diluting Solution D | 50 µl serum |
|-------------------------------|----------------|

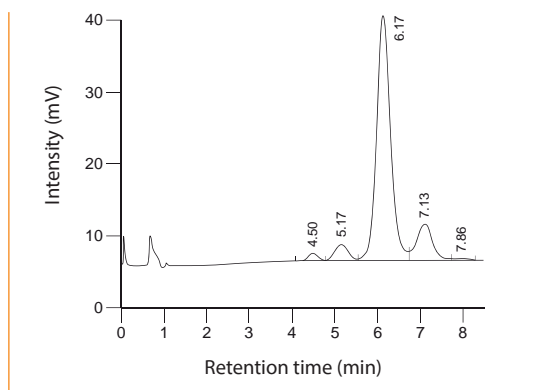
1. incubate (30 min, 4 °C)
2. centrifuge

on-line Analysis:

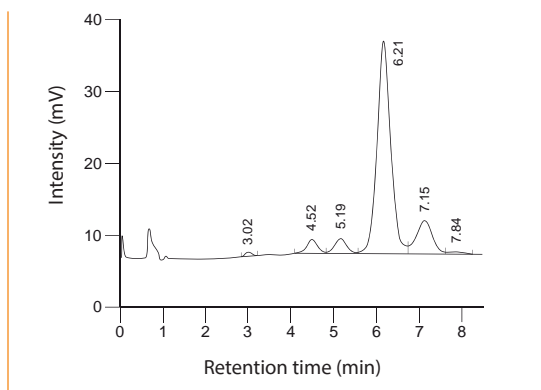
Inject 400 µl

1.1.1. Alcoholism

Native sample, normal range



Native sample, pathological range



Disialotransferrin: 4.50 min, Trisialotransferrin: 5.17 min, Tetrasialotransferrin: 6.17 min, Pentasialotransferrin: 7.13 min, Hexasialotransferrin: 7.86 min

Asialotransferrin: 3.02 min, Disialotransferrin: 4.52 min, Trisialotransferrin: 5.19 min, Tetrasialotransferrin: 6.21 min, Pentasialotransferrin: 7.15 min, Hexasialotransferrin: 7.84 min

Ordering Information

| Order No. | Description | Quantity |
|------------------------------------------|---------------------------------------------------------------------------------|-------------------------|
| 21200 | ClinRep® Complete Kit for CDT in Serum for 300 assays | 1 pce. |
| Kit Components (order no. 21200): | | |
| 21007 | Mobile Phase A | 3 x 21007 (3 x 2000 ml) |
| 21008 | Mobile Phase B | 2000 ml |
| 21009 | Mobile Phase C | 2 x 21009 (2 x 2000 ml) |
| 21021 | Diluting Solution D | 3 x 21221 (3 x 50 ml) |
| | Manual | 1 pce. |
| | Quick Reference | 1 pce. |
| Optional Components: | | |
| 21013 | Serum Calibrator Set, lyophil. (Level 1 - 2) | 2 x 1 x 1 ml |
| 21014 | Test Solution | 15 ml |
| Start Accessories: | | |
| 21030 | Analytical Column with test chromatogram | 1 pce. |
| 21032 | Cartridge incl. 1 precolumn | 1 pce. |
| FK5820 | Stainless steel prefilter holder incl. 1 prefilter | 1 pce. |
| FK7400 | Inline-Filter (stainless steel sieve, free of dead volume) | 1 pce. |
| Refill Service: | | |
| 21031 | Analytical Column with test chromatogram (original column needs to be returned) | 1 pce. |
| Accessories: | | |
| 21033 | Precolumns | 5 pcs. |
| FK6512 | 96-Well-Plates (500 µl) | 8 pcs. |
| FK1102 | Switching valve, Sykam (6-port/3-channel incl. electr. drive, PEEK) | 1 pce. |
| FK5810 | PEEK tubing (connection of prefilter and column) | 1 pce. |
| FK5821 | Replacement filter for stainless steel prefilter holder | 10 pcs. |
| FK7340 | Sealings and sieves for order no. FK7400 | 4 pcs. each |
| FW3000 | Fixed-Wavelength-VIS-Detector (460 nm), complete | 1 pce. |
| RC2002 | Sodium-Hypochlorite-Solution (5 %) | 12 ml |
| ClinChek® Controls: | | |
| 21080 | Serum Control, lyophil., Level I | 10 x 1 ml |
| 21081 | Serum Control, lyophil., Level II | 10 x 1 ml |
| 21082 | Serum Control, lyophil., Level I, II | 2 x 5 x 1 ml |

Catecholamines in Plasma

Epinephrine (E), norepinephrine (NE) and dopamine (D) are termed as catecholamines. The determination of catecholamines is primarily used for helping to detect and rule out pheochromocytomas in symptomatic patients, i.e. in patients with persistent hypertension. It is also used in order to help monitor for recurrence when a pheochromocytoma has been discovered and removed. For these purposes this ClinRep® Complete Kit allows a quick and safe quantification of the catecholamines.

- Reliable sample preparation
- Quick and safe quantification

Test Data

| | |
|-----------------------|----------------------------------------------|
| Linearity: | 15 - 2500 ng/l (NE, E) 30 - 2500 ng/l (D) |
| Recovery: | 70 - 90 % |
| LOD: | 8 ng/l (NE, E), 15 ng/l (D) |
| LLOQ: | 15 ng/l (NE, E), 30 ng/l (D) |
| Intraassay precision: | 6.7 % (NE), 7.6 % (E), 6.1 % (D) |
| Interassay precision: | 5.3 % (NE), 4.2 % (E), 3.9 % (D) |

HPLC Parameters

| | |
|---------------------|------------------------------------------|
| Pump: | isocratic pump, |
| flow rate: | 1.0 ml/min |
| Injection volume: | 40 µl |
| Injection interval: | 15 min |
| EC-Detector: | potential: 500 mV, sensitivity: 10 nA |
| Temperature: | 25 °C |

Sample Preparation

Extraction:

Apply 1 ml plasma and 50 µl Internal Standard IS to a sample preparation column

wash
(3 x 1 ml Washing Solution W)

Elution:

Elute with 120 µl Eluting Reagent E

collect the eluate

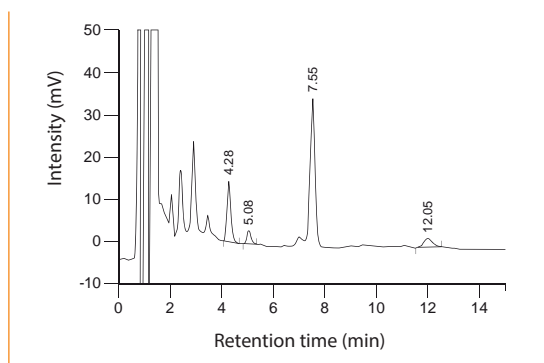
HPLC Analysis:

Inject 40 µl



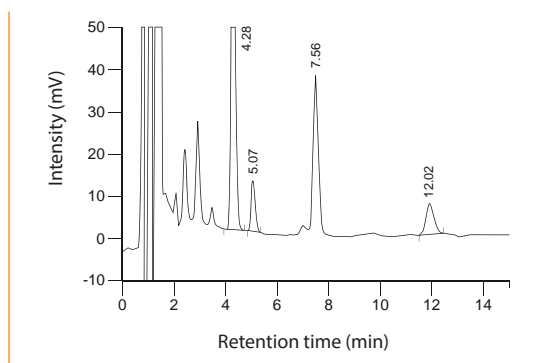
1.1.2. Biogenic Amines

ClinChek® Plasma Control, Level I



Norepinephrine: 4.28 min, Epinephrine: 5.08 min,
IS: 7.55 min, Dopamine: 12.05 min

ClinChek® Plasma Control, Level II



Norepinephrine: 4.28 min, Epinephrine: 5.07 min,
IS: 7.56 min, Dopamine: 12.02 min

Ordering Information

| Order No. | Description | Quantity |
|-----------------------------------------|--------------------------------------------------------------------------|------------------------|
| 1000 | ClinRep® Complete Kit for Catecholamines in Plasma for 250 assays | 1 pce. |
| Kit Components (order no. 1000): | | |
| 1210 | Mobile Phase | 1000 ml |
| 1011 | Standard Solution | 10 ml |
| 1012 | Internal Standard IS | 15 ml |
| 1013 | Plasma Calibrator, lyophil. | 5 x 5 ml |
| 1020 | Sample Preparation Columns incl. Elution vials | 5 x 1020 (5 x 50 pcs.) |
| 1021 | Washing Solution W | 3 x 1021 (3 x 250 ml) |
| 1022 | Eluting Reagent E | 30 ml |
| | Manual | 1 pce. |
| | Quick Reference | 1 pce. |
| Start Accessories: | | |
| 1030 | Analytical Column with test chromatogram | 1 pce. |
| ClinChek® Controls: | | |
| 8810 | Plasma Control, lyophil., Level I | 10 x 5 ml |
| 8811 | Plasma Control, lyophil., Level II | 10 x 5 ml |
| 8809 | Plasma Control, lyophil., Level I, II | 2 x 5 x 5 ml |

Catecholamines in Urine

With this complete kit, the determination of norepinephrine (NE), epinephrine (E) and dopamine (D) is performed from urine. The sample preparation features particular user friendliness for laboratory routine. For a safe and convenient check-up of the pH-value prior to sample extraction, a special stabilising reagent with colour indicator is available. The distinct indicator colouring assures the setting of the appropriate pH value range (pH 2 – 5). Alternatively to this method with manual sample preparation RECIPE offers ClinRep® Complete Kits for use with Gilson automatic pipetting systems.

- Safe and convenient pH-adjustment
- Robust chromatography
- Detection limit: 1 µg/l



Test Data

| | |
|-------------|----------------------------------|
| Linearity: | 2 - 1000 µg/l |
| Recovery: | 70 - 85 % |
| LOD / LLOQ: | 1 µg/l / 2 µg/l |
| Precision | |
| Intraassay: | 0.8 % (NE), 1.4 % (E), 1.7 % (D) |
| Interassay: | 2.0 % (NE), 2.3 % (E), 3.1 % (D) |

HPLC Parameters

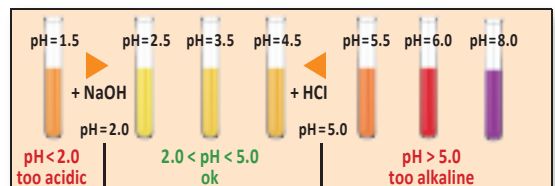
| | |
|----------------------|---------------------------|
| Isocratic Pump: | flow rate: 1.0 ml/min |
| Injection vol./int.: | 20 µl / 15 min |
| EC-Detector: | pot.: 500 mV, sen.: 10 nA |
| HPLC-Thermostat: | 30 °C |

Sample Preparation

Addition of IS/ pH adjustment:

| | | |
|---------------|--------------------------------------------------|-------------------------------|
| 3 ml urine | 5 ml Stab. Reagent S (contains colour indic.) | 30 µl Internal Standard IS |
|---------------|--------------------------------------------------|-------------------------------|

adjust with 1 M NaOH,
until the indicator switches to yellow



Extraction:

| |
|------------------------------------------------------------|
| Apply the whole sample on the sample preparation column |
|------------------------------------------------------------|

wash (HPLC water)

Elution:

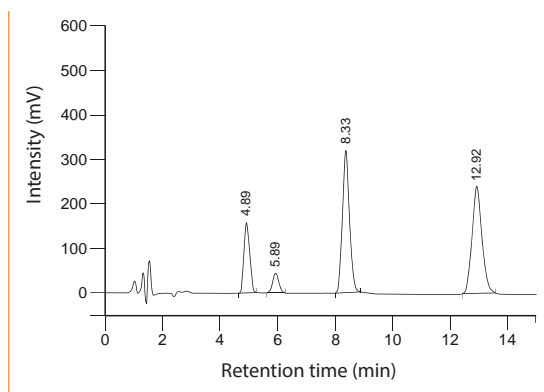
| |
|------------------------------|
| Apply 6 ml Eluting Reagent E |
|------------------------------|

HPLC Analysis:

| |
|--------------|
| Inject 20 µl |
|--------------|

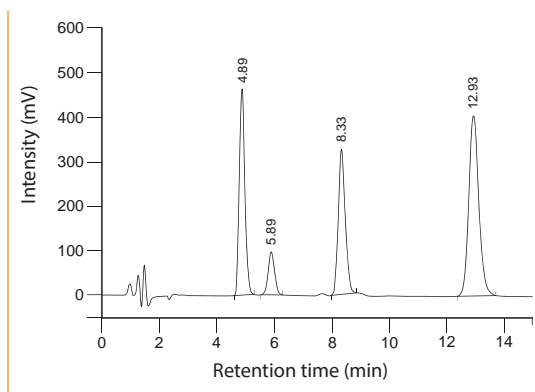
1.1.2. Biogenic Amines

ClinChek® Urine Control, Level I



Norepinephrine: 4.89 min, Epinephrine: 5.89 min,
IS: 8.33 min, Dopamine: 12.92 min

ClinChek® Urine Control, Level II



Norepinephrine: 4.89 min, Epinephrine: 5.89 min,
IS: 8.33 min, Dopamine: 12.93 min

Ordering Information

| Order No. | Description | Quantity |
|-----------------------------------------|-------------------------------------------------------------------------|------------------------|
| 2000 | ClinRep® Complete Kit for Catecholamines in Urine for 100 assays | 1 pce. |
| Kit Components (order no. 2000): | | |
| 1210 | Mobile Phase | 1000 ml |
| 2011 | Standard Solution | 10 ml |
| 2012 | Internal Standard IS | 3 ml |
| 2013 | Urine Calibrator, lyophil. | 5 x 8 ml |
| 2020 | Sample Preparation Columns | 2 x 2020 (2 x 50 pcs.) |
| 2021 | Stabilising Reagent S | 500 ml |
| 2024 | Eluting Reagent E | 2 x 2024 (2 x 300 ml) |
| | Manual | 1 pce. |
| | Quick Reference | 1 pce. |
| Start Accessories: | | |
| 2030 | Analytical Column with test chromatogram | 1 pce. |
| Accessories: | | |
| FK4000 | Column Rack (for 20 columns) | 1 pce. |
| ClinChek® Controls: | | |
| 8820 | Urine Control, lyophil., Level I | 10 x 8 ml |
| 8821 | Urine Control, lyophil., Level II | 10 x 8 ml |
| 8822 | Urine Control, lyophil., Level I, II | 2 x 5 x 8 ml |

Catecholamines in Urine

► with Gilson ASPEC™

Catecholamines are important parameters for the diagnosis of pheochromocytomas. In addition to the ClinRep® Complete Kit with manual sample preparation (order no. 2000) RECIPE offers ClinRep® Complete Kits for automated sample preparation with Gilson robotic systems. Kits for 100 and 500 assays are available.

- Automated sample preparation
- Test kits available for 100 or 500 assays
- Injection interval: 15 min



Test Data

Test data are available on request.

HPLC Parameters

Identical with order no. 2000

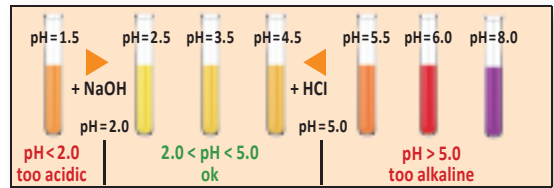
Sample Preparation*

Manual sample pretreatment

pH adjustment:

| | |
|------------|-----------------------------------------------|
| 3 ml urine | 5 ml Stab. Reagent S (contains colour indic.) |
|------------|-----------------------------------------------|

adjust with 1 M NaOH, until the indicator switches to yellow



Automated sample preparation

with Gilson ASPEC™

Addition of IS:

Add 30 µl Internal Standard IS to the sample

Extraction:

Apply 6 ml sample on the sample preparation column

wash (HPLC water)

Elution:

Apply 4 ml Eluting Reagent E

HPLC Analysis:

Inject 20 µl

* The indicated sample/reagent volumes are exemplified for the ASPEC™.

Ordering Information

| Order No. | Description | Quantity |
|-----------------------------------------|--------------------------------------------------------------------------------------------|------------------------|
| 2200 | ClinRep® Complete Kit for Catecholamines in Urine with Gilson ASPEC™ for 100 assays | 1 pce. |
| Kit components (order no. 2200): | | |
| 1210 | Mobile Phase | 1000 ml |
| 2011 | Standard Solution | 10 ml |
| 2012 | Internal Standard IS | 3 ml |
| 2013 | Urine Calibrator, lyophil. | 5 x 8 ml |
| 2220 | Sample Preparation Columns | 2 x 2220 (2 x 50 pcs.) |
| 2021 | Stabilising Reagent S | 500 ml |
| 2224 | Eluting Reagent E | 400 ml |
| | Manual | |
| | Quick Reference | |
| 2300 | ClinRep® Complete Kit for Catecholamines in Urine with Gilson ASPEC™ for 500 assays | 1 pce. |
| Kit components (order no. 2300): | | |
| | 5-fold amount of kit components with order no. 2200 (1210, 2011, ..., 2224) | 5 x 2200 |
| Components for 2200, 2300 | | |
| Start Accessories: | | |
| 2030 | Analytical Column with test chromatogram | 1 pce. |
| ClinChek® Controls: | | |
| 8820 | Urine Control, lyophil., Level I | 10 x 8 ml |
| 8821 | Urine Control, lyophil., Level II | 10 x 8 ml |
| 8822 | Urine Control, lyophil., Level I, II | 2 x 5 x 8 ml |

Catecholamines in Urine

► on-line Analysis

This ClinRep® Complete Kit is designed for the convenient on-line SPE analysis of the catecholamines. A time-consuming manual sample preparation is not required with this method. Prior to the on-line analysis the samples simply have to be spiked with the internal standard (one step sample pretreatment).

- On-line sample preparation
- Robust chromatography with fluorescence detection



Test Data

| | |
|-----------------------|-------------------------------------|
| Linearity: | 3 - 1500 µg/l |
| Recovery: | 95 - 100 % |
| LOD: | 1 µg/l |
| LLOQ: | 3 µg/l |
| Intraassay precision: | 3.0 % (NE), 4.5 % (E), 0.8 % (D) |
| Interassay precision: | 3.6 % (NE), 6.4 % (E), 2.4 % (D) |

HPLC Parameters

| | |
|---------------------------|--------------------------------------------------------|
| Pump 1 (SPE-buffer): | isocratic pump, flow rates: 0.5, 2.0 ml/min |
| Pump 2 (mobile phase): | isocratic pump, flow rate: 1.2 ml/min |
| Switching valve: | 6-port/3-channel switching valve (order no. FK1102) |
| Injection volume: | 50 µl |
| Injection interval: | 20 min |
| Fluorescence detector: | 275 nm (exc.), 330 nm (em.) |
| HPLC-Thermostat: | 30 °C |

Sample Pretreatment

Addition of IS:

Add 20 µl Internal Standard IS/ml urine

centrifuge

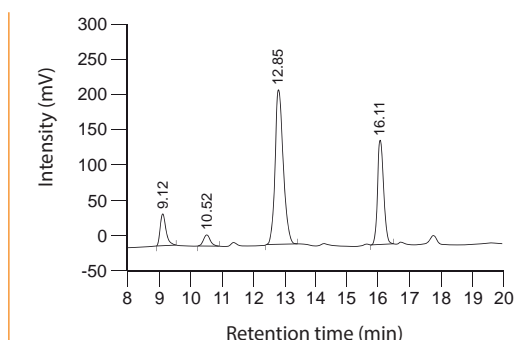
on-line Analysis:

Inject 50 µl

NE: Norepinephrine
E: Epinephrine
D: Dopamine

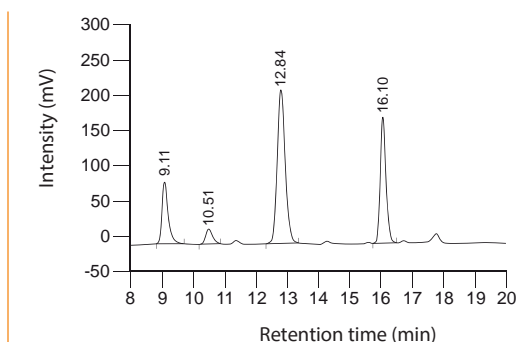
1.1.2. Biogenic Amines

ClinChek® Urine Control, Level I (+ 20 µl IS/ml urine)



Norepinephrine: 9.12 min, Epinephrine: 10.52 min,
IS: 12.85 min, Dopamine: 16.11 min

ClinChek® Urine Control, Level II (+ 20 µl IS/ml urine)



Norepinephrine: 9.11 min, Epinephrine: 10.51 min,
IS: 12.84 min, Dopamine: 16.10 min

Ordering Information

| Order No. | Description | Quantity |
|-----------------------------------------|-------------------------------------------------------------------------|------------------------|
| 2100 | ClinRep® Complete Kit for Catecholamines in Urine for 500 assays | 1 pce. |
| Kit components (order no. 2100): | | |
| 2109 | SPE-Buffer | 4 x 2109 (4 x 2500 ml) |
| 2110 | Mobile Phase | 6 x 2110 (6 x 2500 ml) |
| 2011 | Standard Solution | 10 ml |
| 2113 | Urine Calibrator, lyophil. | 5 x 8 ml |
| | Manual | 1 pce. |
| | Quick Reference | 1 pce. |
| Optional components: | | |
| 2012 | Internal Standard IS | 3 ml |
| Start Accessories: | | |
| 1232 | Guard Column Holder | 1 pce. |
| 1233 | Guard Columns | 4 pcs. |
| 2130 | Analytical Column with test chromatogram | 1 pce. |
| 2131 | SPE-Column | 1 pce. |
| FK5810 | PEEK capillary connector (connection of prefilter and column) | 1 pce. |
| FK5820 | Stainless steel prefilter holder incl. 1 prefilter | 1 pce. |
| FK7400 | Inline-Filter (stainless steel sieve, free of dead volume) | 1 pce. |
| Accessories: | | |
| FK1102 | Switching valve, Sykam (6-port/3-channel incl. electr. drive, PEEK) | 1 pce. |
| FK5821 | Replacement filter for stainless steel prefilter holder | 10 pcs. |
| FK7340 | Sealings and sieves for order no. FK7400 | 4 pcs. each |
| ClinChek® Controls: | | |
| 2182 | Urine Control (FD), lyophil., Level I, II | 2 x 5 x 5 ml |

Metanephrines in Urine

Metanephrines, i.e. metanephrine (M), normetanephrine (NM) and 3-methoxytyramine (MT), are the primary metabolites of the catecholamines. Similar to the catecholamines, the determination of the metanephrines is used to detect or rule out tumors of the sympathoadrenal system. For this purpose the RECIPE test kit features particular user friendliness within sample preparation. For a safe and convenient check-up of the pH-value prior to sample extraction, a special diluting solution with colour indicator is available. The distinct colouring of the indicator assures that the analyte extraction is performed under appropriate pH conditions ($\text{pH} > 6$). Also available: Test kits for automated sample preparation.

- Safe and convenient pH-adjustment
- Robust chromatography



Test Data

| | |
|-------------|---------------------------------------|
| Linearity: | 8 - 10000 $\mu\text{g/l}$ |
| Recovery: | 60 % |
| LOD / LLOQ: | 5 $\mu\text{g/l}$ / 8 $\mu\text{g/l}$ |
| Precision | |
| Intraassay: | 1.7 % (NM), 3.0 % (M), 2.5 % (MT) |
| Interassay: | 1.8 % (NM), 2.9 % (M), 1.9 % (MT) |

HPLC Parameters

| | |
|----------------------|-------------------------|
| Isoocratic Pump: | flow rate 1.3 ml/min |
| Injection vol./int.: | 20 μl /8 min |
| EC-Detector: | pot. 650mV, sen.: 50 nA |
| HPLC-Thermostat: | 30 $^{\circ}\text{C}$ |

Sample Preparation

Hydrolysis:

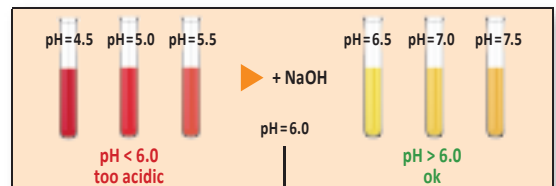
| | |
|------------|---------------------------------------|
| 1 ml urine | 20 μl Internal Standard IS |
|------------|---------------------------------------|

1. adjust pH to 0.5 - 1.0
2. incubate (30 min, 90 - 100 $^{\circ}\text{C}$)

pH adjustment:

Add 4 ml Diluting Solution D (contains colour indicator)

check, if the sample is yellow ($\text{pH} > 6$)
if necessary, add 1 M NaOH dropwise



Extraction:

Apply the whole sample on the sample preparation column

Washing:

Wash (HPLC water and Washing Solution W)

Elution:

Elute with 5 ml Eluting Reagent E
(receiver vial: 1 ml Stabilising Reagent S)

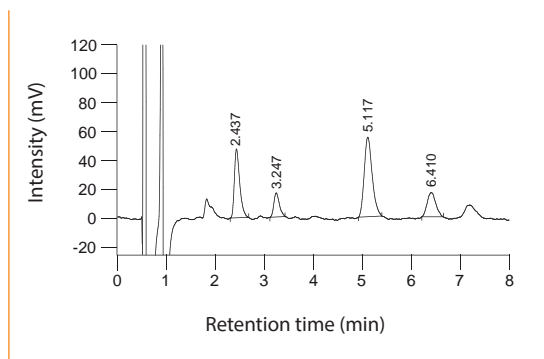
collect the eluate

HPLC Analysis:

Inject 20 μl

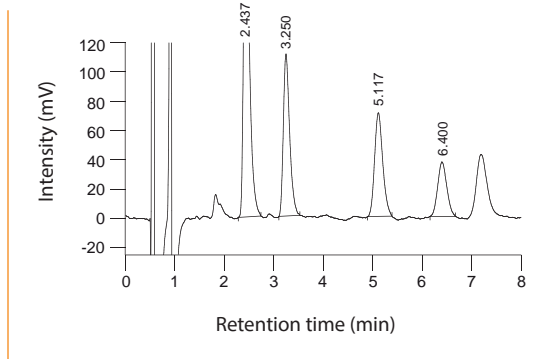
1.1.2. Biogenic Amines

ClinChek® Urine Control, Level I



Normetanephrine: 2.437 min, Metanephrine: 3.247 min, IS: 5.117 min, 3-Methoxytyramine: 6.410 min

ClinChek® Urine Control, Level II



Normetanephrine: 2.437 min, Metanephrine: 3.250 min, IS: 5.117 min, 3-Methoxytyramine: 6.400 min

Ordering Information

| Order No. | Description | Quantity |
|-----------------------------------------|-------------------------------------------------------------------------------------|------------------------|
| 4000 | ClinRep® Complete Kit for Metanephrines in Urine for 100 assays | 1 pce. |
| Kit components (order no. 4000): | | |
| 4010N | Mobile Phase | 1000 ml |
| 4011N | Standard Solution | 10 ml |
| 4012N | Internal Standard IS | 3 ml |
| 4013 | Urine Calibrator, lyophil. | 5 x 8 ml |
| 4020 | Sample Preparation Columns | 2 x 4020 (2 x 50 pcs.) |
| 4022 | Diluting Solution D | 400 ml |
| 4023 | Washing Solution W | 400 ml |
| 4024 | Eluting Reagent E | 2 x 4024 (2 x 250 ml) |
| 4025 | Stabilising Reagent S | 100 ml |
| | Manual | 1 pce. |
| | Quick Reference | 1 pce. |
| Start Accessories: | | |
| 4030N | Analytical Column with test chromatogram | 1 pce. |
| Accessories: | | |
| FK4000 | Column Rack (for 20 columns) | 1 pce. |
| FK6300 | Reagent tube (100 x 16 mm) with screw cap and o-ring, PP, autoclavable up to 121 °C | 50 pcs. |
| ClinChek® Controls: | | |
| 8820 | Urine Control, lyophil., Level I | 10 x 8 ml |
| 8821 | Urine Control, lyophil., Level II | 10 x 8 ml |
| 8822 | Urine Control, lyophil., Level I, II | 2 x 5 x 8 ml |

1.1.2. Biogenic Amines

Metanephrines in Urine

► with Gilson ASPEC™

Metanephrines are important parameters for the diagnosis of tumors of the sympathoadrenal system. In addition to the ClinRep® Complete Kit with manual sample preparation (order no. 4000) RECIPE offers ClinRep® Complete Kits for automated sample preparation with Gilson robotic systems. Kits for 100 and 500 assays are available.

- Automated sample preparation
- Test kits available for 100 or 500 assays



Test Data

Test data are available on request.

HPLC Parameters

Identical with order no. 4000

Sample Preparation*

Manual sample pretreatment Hydrolysis:

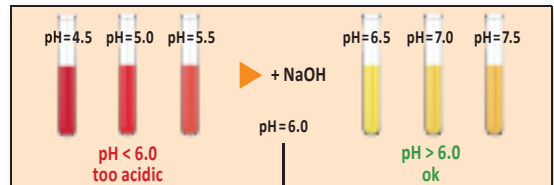
| | |
|------------|----------------------------|
| 1 ml urine | 20 µl Internal Standard IS |
|------------|----------------------------|

1. adjust pH to 0.5 - 1.0
2. incubate (30 min, 90 - 100 °C)

pH adjustment:

Add 4 ml Diluting Solution D (contains colour indicator)

check, if the sample is yellow (pH > 6)
if necessary, add 1 M NaOH dropwise



Automated sample preparation with Gilson ASPEC™

Extraction:

Apply 2.5 ml sample to the sample preparation column

wash (HPLC water and Washing Solution W)

Elution:

Elute with 2.5 ml Eluting Reagent E
(receiver vial: 800 µl Stabilising Reagent S)

collect the eluate

HPLC Analysis:

Inject 20 µl

* The indicated sample/reagent volumes are exemplified for the ASPEC™.

Ordering Information

| Order No. | Description | Quantity |
|-----------------------------------------|-------------------------------------------------------------------------------------------|------------------------|
| 4100 | ClinRep® Complete Kit for Metanephrines in Urine with Gilson ASPEC™ for 100 assays | 1 pce. |
| Kit components (order no. 4100): | | |
| 4010N | Mobile Phase | 1000 ml |
| 4011N | Standard Solution | 10 ml |
| 4012N | Internal Standard IS | 3 ml |
| 4013 | Urine Calibrator, lyophil. | 5 x 8 ml |
| 4120 | Sample Preparation Columns | 2 x 4120 (2 x 50 pcs.) |
| 4022 | Diluting Solution D | 400 ml |
| 4023 | Washing Solution W | 400 ml |
| 4124 | Eluting Reagent E | 250 ml |
| 4125 | Stabilising Reagent S | 80 ml |
| | Manual | 1 pce. |
| | Quick Reference | 1 pce. |
| 4200 | ClinRep® Complete Kit for Metanephrines in Urine with Gilson ASPEC™ for 500 assays | 1 pce. |
| Kit components (order no. 4200): | | |
| | 5-fold amount of kit components with order no. 4100 (4010, 4011, ..., 4125) | 5 x 4100 |
| Components for 4100, 4200 | | |
| Start Accessories: | | |
| 4030N | Analytical Column with test chromatogram | 1 pce. |
| Accessories: | | |
| FK6300 | Reagent tubes (100 x 16 mm) with screw cap and o-ring, PP, autoclavable up to 121 °C | 50 pcs. |
| ClinChek® Controls: | | |
| 8820 | Urine Control, lyophil., Level I | 10 x 8 ml |
| 8821 | Urine Control, lyophil., Level II | 10 x 8 ml |
| 8822 | Urine Control, lyophil., Level I, II | 2 x 5 x 8 ml |

Serotonin in Plasma

Serotonin is a neurotransmitter in the central nervous system. Serotonin deficiencies are connected with disorders such as depression, schizophrenia and Parkinson's disease. Moreover serotonin is produced in excess by carcinoid tumors. The determination of serotonin, together with its metabolite 5-HIAA, is used to confirm or rule out a tumor. The RECIPE test kit allows a quick and sensitive determination of serotonin from platelet-rich plasma, platelet-poor plasma and serum. An additional test kit is available for the determination from urine.

- Quick sample preparation
- Injection interval: 10 min
- High analytical sensitivity



Test Data

| | |
|-----------------------|----------------|
| Linearity: | 0.7 - 662 µg/l |
| Recovery: | 90 - 100 % |
| LOD: | 0.2 µg/l |
| LLOQ: | 0.6 µg/l |
| Intraassay precision: | 1.9 % |
| Interassay precision: | 4.0 % |

HPLC Parameters

| | |
|---------------------|------------------------------------------|
| Pump: | isocratic pump, flow rate: 1.0 ml/min |
| Injection volume: | 20 µl |
| Injection interval: | 10 min |
| EC-Detector: | potential: 450 mV, sensitivity: 20 nA |
| HPLC-Thermostat: | 30 °C |

Sample Preparation

Precipitation:

| | |
|------------------|-------------------------------|
| 200 µl plasma | 10 µl Internal Standard IS |
|------------------|-------------------------------|

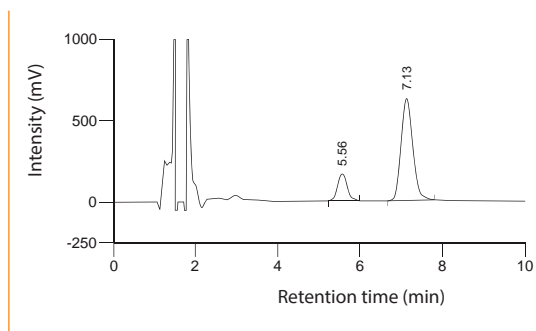
1. add 200 µl Precipitant P
2. centrifuge

HPLC Analysis:

| |
|--------------|
| Inject 20 µl |
|--------------|

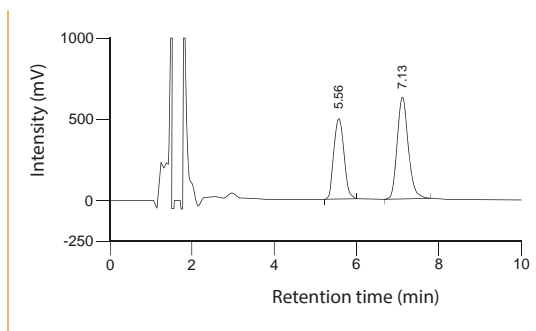
1.1.2. Biogenic Amines

ClinChek® Plasma Control, Level I



Serotonin: 5.56 min, IS: 7.13 min

ClinChek® Plasma Control, Level II



Serotonin: 5.56 min, IS: 7.13 min

Ordering Information

| Order No. | Description | Quantity |
|-----------------------------------------|--------------------------------------------------------------|--------------|
| 6000 | ClinRep® Complete Kit for Serotonin in Plasma for 100 assays | 1 pce. |
| Kit components (order no. 6000): | | |
| 6710 | Mobile Phase | 1000 ml |
| 6711 | Standard Solution, lyophil. | 5 x 2 ml |
| 6712 | Internal Standard IS, lyophil. | 5 x 1 ml |
| 6013 | Plasma Calibrator, lyophil. | 5 ml |
| 6020 | Sample Preparation Vials | 100 pcs. |
| 6021 | Precipitant P | 22 ml |
| | Manual | 1 pce. |
| | Quick Reference | 1 pce. |
| Start Accessories: | | |
| 6030 | Analytical Column with test chromatogram | 1 pce. |
| ClinChek® Controls: | | |
| 8810 | Plasma Control, lyophil., Level I | 10 x 5 ml |
| 8811 | Plasma Control, lyophil., Level II | 10 x 5 ml |
| 8809 | Plasma Control, lyophil., Level I, II | 2 x 5 x 5 ml |

Serotonin in Urine

Serotonin is an important neurotransmitter. The main metabolite of serotonin is 5-hydroxyindole acetic acid (5-HIAA) which is excreted with urine. Patients with carcinoid tumors usually show increased levels of serotonin in plasma and urine as well as of 5-HIAA in urine. As some tumors show a decreased serotonin turnover (e.g. AADC-deficient tumors), low 5-HIAA levels must be verified by the determination of serotonin. The RECIPE test kit provides a highly selective sample preparation and guarantees a reliable chromatography.

- Highly selective sample clean up
- Reliable chromatography
- Injection interval: 10 min



Test Data

| | |
|-----------------------|---------------|
| Linearity: | 5 - 1000 µg/l |
| Recovery: | 70 - 85 % |
| LOD: | 3 µg/l |
| LLOQ: | 5 µg/l |
| Intraassay precision: | 3 % |
| Interassay precision: | 4 % |

HPLC Parameters

| | |
|---------------------|------------------------------------------|
| Pump: | isocratic pump, flow rate: 1.0 ml/min |
| Injection volume: | 20 µl |
| Injection interval: | 10 min |
| EC-Detector: | potential: 450 mV, sensitivity: 50 nA |
| HPLC-Thermostat: | 30 °C |

Sample Preparation

Dilution:

| | | |
|---------------|-------------------------------|-------------------------------|
| 2 ml urine | 4 ml Stabilising Reagent S | 50 µl Internal Standard IS |
|---------------|-------------------------------|-------------------------------|

adjust pH to 4.5 - 6.5



Extraction:

Apply the whole sample on
the sample preparation column

wash (HPLC water and Washing Solution W)



Elution:

Apply 5 ml Eluting Reagent E

collect the eluate

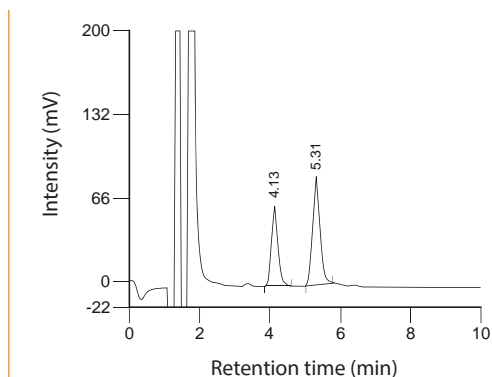


HPLC Analysis:

Inject 20 µl

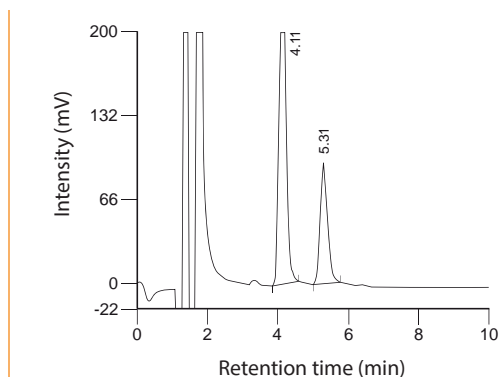
1.1.2. Biogenic Amines

ClinChek® Urine Control, Level I



Serotonin: 4.13 min, IS: 5.31 min

ClinChek® Urine Control, Level II



Serotonin: 4.11 min, IS: 5.31 min

Ordering Information

| Order No. | Description | Quantity |
|-----------------------------------------|--------------------------------------------------------------------|------------------------|
| 7000 | ClinRep® Complete Kit for Serotonin in Urine for 100 assays | 1 pce. |
| Kit components (order no. 7000): | | |
| 6710 | Mobile Phase | 1000 ml |
| 6711 | Standard Solution, lyophil. | 5 x 2 ml |
| 6712 | Internal Standard IS, lyophil. | 5 x 1 ml |
| 7013 | Urine Calibrator, lyophil. | 5 x 8 ml |
| 7020 | Sample Preparation Columns | 2 x 7020 (2 x 50 pcs.) |
| 7021 | Stabilising Reagent S | 2 x 7021 (2 x 200 ml) |
| 7022 | Washing Solution W | 200 ml |
| 7023 | Eluting Reagent E | 500 ml |
| | Manual | 1 pce. |
| | Quick Reference | 1 pce. |
| Start Accessories: | | |
| 7030 | Analytical Column with test chromatogram | 1 pce. |
| Accessories: | | |
| FK4000 | Column Rack (for 20 columns) | 1 pce. |
| ClinChek® Controls: | | |
| 8820 | Urine Control, lyophil., Level I | 10 x 8 ml |
| 8821 | Urine Control, lyophil., Level II | 10 x 8 ml |
| 8822 | Urine Control, lyophil., Level I, II | 2 x 5 x 8 ml |

1.1.2. Biogenic Amines

VMA, HVA and 5-HIAA in Urine

Vanillylmandelic acid (VMA) and homovanillic acid (HVA) are end-products of the catecholamine metabolism. The determination of VMA and HVA in urine serves as a screening test for neuroblastoma, one of the most common solid tumors in early childhood. 5-hydroxyindoleacetic acid (5-HIAA) is a metabolite of serotonin and is used for the diagnosis of carcinoid tumors. The RECIPE ClinRep® Complete Kit allows a reliable determination of VMA, HVA and 5-HIAA in only 15 min time for analysis.

Also available: Complete kits for automated sample preparation.

- Highly selective sample preparation
- Injection interval: 15 min
- Reliable test procedure

Test Data

| | |
|-------------|---------------------------------------------------------------------|
| Linearity: | VMA: 0.6 - 100 mg/l HVA: 0.3 - 100 mg/l 5-HIAA: 0.2 - 50 mg/l |
| Recovery: | 75 - 90 % |
| LOD: | VMA: 0.2 mg/l HVA: 0.1 mg/l 5-HIAA: 0.1 mg/l |
| LLOQ: | VMA: 0.6 mg/l HVA: 0.3 mg/l 5-HIAA: 0.2 mg/l |
| Precision | |
| Intraassay: | 2.6 % (VMA), 2.5 % (HVA), 3.0 % (5-HIAA) |
| Interassay: | 3.7 % (VMA), 3.8 % (HVA), 3.6 % (5-HIAA) |

HPLC Parameters

| | |
|------------------------|---------------------------|
| Isocratic Pump: | flow rate: 0.9 ml/min |
| Injection vol. / int.: | 20 µl / 15 min |
| EC-Detector: | pot.: 800 mV, sen.: 50 nA |
| HPLC-Thermostat: | 30 °C |

Sample Preparation

Addition of IS:

50 µl urine

1 ml Internal Standard IS

Extraction:

Apply the whole sample on the sample preparation column

1. wash with 1 ml Ammonia Solution A
2. fill up with Boric Acid B

Elution:

Apply 2 ml Eluting Reagent E

collect the eluate

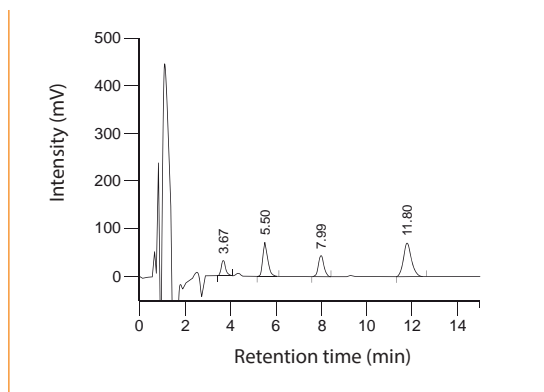
HPLC Analysis:

Inject 20 µl



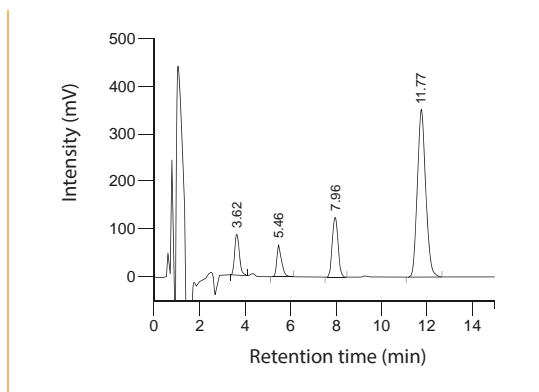
1.1.2. Biogenic Amines

ClinChek® Urine Control, Level I



VMA: 3.67 min, IS: 5.50 min, HVA: 7.99 min,
5-HIAA: 11.80 min

ClinChek® Urine Control, Level II



VMA: 3.62 min, IS: 5.46 min, HVA: 7.96 min,
5-HIAA: 11.77 min

Ordering Information

| Order No. | Description | Quantity |
|-----------------------------------------|---------------------------------------------------------------------------|------------------------|
| 3000 | ClinRep® Complete Kit for VMA, HVA, 5-HIAA in Urine for 100 assays | 1 pce. |
| Kit components (order no. 3000): | | |
| 3010 | Mobile Phase | 1000 ml |
| 3011 | Standard Solution, lyophil. | 5 x 1 ml |
| 3012 | Internal Standard IS | 100 ml |
| 3013 | Urine Calibrator, lyophil. | 5 x 5 ml |
| 3020 | Sample Preparation Columns | 2 x 3020 (2 x 50 pcs.) |
| 3021 | Ammonia Solution A | 100 ml |
| 3022 | Boric Acid Solution B | 2 x 3022 (2 x 300 ml) |
| 3023 | Eluting Reagent E | 2 x 3023 (2 x 100 ml) |
| | Manual | 1 pce. |
| | Quick Reference | 1 pce. |
| Start Accessories: | | |
| 3030 | Analytical Column with test chromatogram | 1 pce. |
| ClinChek® Controls: | | |
| 8820 | Urine Control, lyophil., Level I | 10 x 8 ml |
| 8821 | Urine Control, lyophil., Level II | 10 x 8 ml |
| 8822 | Urine Control, lyophil., Level I, II | 2 x 5 x 8 ml |

1.1.2. Biogenic Amines

VMA, HVA and 5-HIAA in Urine

► with Gilson ASPEC™

VMA, HVA and 5-HIAA are important parameters for the diagnosis of neuroblastoma and carcinoid tumors. In addition to the ClinRep® Complete Kit with manual sample preparation (order no. 3000) RECIPE offers ClinRep® Complete Kits for automated sample preparation with Gilson robotic systems. Kits for 100 and 500 assays are available.

- Automated sample preparation
- Test kits available for 100 or 500 assays
- Injection interval: 15 min



Test Data

Test data are available on request.

HPLC Parameters

Identical with order no. 3000

Sample Preparation*

Automated sample preparation with Gilson ASPEC™

Addition of IS:

| | |
|-------------|---------------------------|
| 50 µl urine | 1 ml Internal Standard IS |
|-------------|---------------------------|



Extraction:

| |
|----------------------------------------------------|
| Apply 1 ml sample on the sample preparation column |
|----------------------------------------------------|

1. wash with 1 ml Ammonia Solution A
2. wash with 2.5 ml Boric Acid B



Elution:

| |
|------------------------------|
| Apply 2 ml Eluting Reagent E |
|------------------------------|



HPLC Analysis:

| |
|--------------|
| Inject 20 µl |
|--------------|

* The indicated sample/reagent volumes are exemplified for the ASPEC™.



Ordering Information

| Order No. | Description | Quantity |
|-----------------------------------------|--------------------------------------------------------------------------------------------------------------------|------------------------|
| 3100 | ClinRep[®] Complete Kit for VMA, HVA, 5-HIAA in Urine with Gilson ASPEC[™] for 100 assays | 1 pce. |
| Kit components (order no. 3100): | | |
| 3010 | Mobile Phase | 1000 ml |
| 3011 | Standard Solution, lyophil. | 5 x 1 ml |
| 3012 | Internal Standard IS | 100 ml |
| 3013 | Urine Calibrator, lyophil. | 5 x 5 ml |
| 3120 | Sample Preparation Columns | 2 x 3120 (2 x 50 pcs.) |
| 3021 | Ammonia Solution A | 100 ml |
| 3022 | Boric Acid Solution B | 2 x 3022 (2 x 300 ml) |
| 3023 | Eluting Reagent E | 2 x 3023 (2 x 100 ml) |
| | Manual | 1 pce. |
| | Quick Reference | 1 pce. |
| 3200 | ClinRep[®] Complete Kit for VMA, HVA, 5-HIAA in Urine with Gilson ASPEC[™] for 500 assays | 1 pce. |
| Kit components (order no. 3200): | | |
| | 5-fold amount of kit components with order no. 3100 (3010, 3011, ..., 3023) | 5 x 3100 |
| Components for 3100, 3200 | | |
| Start Accessories: | | |
| 3030 | Analytical Column with test chromatogram | 1 pce. |
| ClinChek[®] Controls: | | |
| 8820 | Urine Control, lyophil., Level I | 10 x 8 ml |
| 8821 | Urine Control, lyophil., Level II | 10 x 8 ml |
| 8822 | Urine Control, lyophil., Level I, II | 2 x 5 x 8 ml |

Hemoglobin Variants and β -Thalassemia Screening in Whole Blood

Defects in genes, which are responsible for the synthesis of the hemoglobin molecule, result in a group of hereditary diseases termed as "hemoglobinopathies". Depending on the molecular defect, hemoglobinopathies may be classified in "structural hemoglobin variants" and in "thalassemias". This test kit allows a reliable separation and identification of the common and clinically significant hemoglobin variants. For β -thalassemia screening the kit ensures an exact quantification of HbF and HbA2. A ready for use test solution (containing: HbA1c, HbF, HbA0, HbE, HbA2, HbD, HbS, HbC), a hemolysate calibrator (containing: HbF, HbA2) as well as hemolysate controls in two levels of concentration are available for quality assurance.

- Reliable separation and quantification of HbA2 and HbF
- Safe identification of HbS, HbC, HbE and HbD
- Test solution, calibrator and control materials available



Test Data

| | |
|-----------------------|-----------------------------------------|
| Intraassay precision: | 1.0 - 3.3 % (HbF) 0.6 - 3.6 % (HbA2) |
| Interassay precision: | 2.1 - 2.8 % (HbF) 0.7 - 2.4 (HbA2) |

Dependence on total hemoglobin:

The HbF and HbA2 values are independent on the amount of total hemoglobin in a range from 6 - 24 g/dl total hemoglobin.

HPLC Parameters

| | |
|---------------------|----------------------|
| Pump: | binary gradient pump |
| Flow rate: | 1.2 ml/min |
| Injection volume: | 20 μ l |
| Injection interval: | 8 min |
| UV/VIS-Detector: | 415 nm |
| HPLC-Thermostat: | 23 °C |

Sample Preparation

Hemolysis:

| | |
|------------------------|-----------------------------|
| 5 μ l venous blood | 1.25 ml Hemolysis Reagent H |
|------------------------|-----------------------------|

incubate (10 min, ambient temp.)



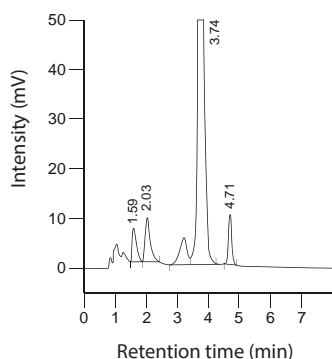
HPLC Analysis:

Inject 20 μ l



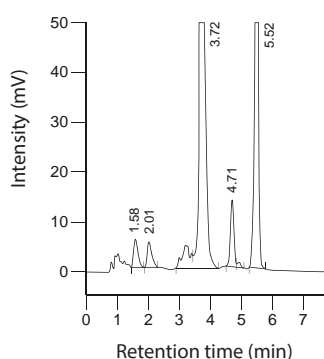
1.1.3. Hemoglobins

ClinCal® Hemolysate Calibrator (HbF/A2)



HbA1c: 1.59 min, HbF: 2.03 min, HbA0: 3.74 min,
HbA2: 4.71 min

ClinCheck® Hemolysate Control (HbF/A2/S), Level I



HbA1c: 1.58 min, HbF: 2.01 min, HbA0: 3.72 min,
HbA2: 4.71, HbS: 5.52 min

Ordering Information

| Order No. | Description | Quantity |
|----------------------------------------------------------|----------------------------------------------------------------------------------------------------------------|--------------|
| 13100 | ClinRep® Complete Kit for Hemoglobin Variants and β -Thalassemia Screening in Whole Blood for 500 assays | 1 pce. |
| Components of the Complete Kit (order no. 13100): | | |
| 13101 | ClinRep® Reagent Kit | 1 pce. |
| 13113 | Hemolysate Calibrator HbF/A2, ready for use | 5 x 3 ml |
| 13130 | Analytical Column with test chromatogram | 1 pce. |
| | Manual | 1 pce. |
| | Quick Reference | 1 pce. |
| Components of the Reagent Kit (order no. 13101): | | |
| 13107 | Buffer 1 | 2500 ml |
| 13108 | Buffer 2 | 2500 ml |
| 13109 | Washing Solution W | 2000 ml |
| 13121 | Hemolysis Reagent H | 500 ml |
| Optional Components: | | |
| 13114 | Test Solution (HbA1c/F/A/E/A2/D/S/C), ready for use | 5 x 3 ml |
| Accessories: | | |
| 11024 | Sample vials 1.5 ml without cap | 1000 pcs. |
| FK5810 | PEEK tubing (connection of prefilter and column) | 1 pce. |
| FK5820 | Stainless steel prefilter holder incl. 1 prefilter | 1 pce. |
| FK5821 | Replacement filter for stainless steel prefilter holder | 10 pcs. |
| ClinChek® Controls: | | |
| 13182 | Hemolysate Control HbF/A2, Level I, II, ready for use | 2 x 5 x 3 ml |
| 13183 | Hemolysate Control HbF/A2/S, Level I, ready for use | 5 x 3 ml |

Aromatic Amino Acids in Plasma

Several metabolic disorders result from an impaired amino acid metabolism. Furthermore, some forms of depression seem to be connected with alterations of the metabolism of tyrosine and tryptophan, these being the precursors of the brain neurotransmitters epinephrine, norepinephrine, dopamine and serotonin. The ClinRep® Complete Kit serves for the analysis of the amino acids phenylalanine, tyrosine and tryptophan and may be used for the monitoring of the blood plasma level within a dietary therapy.

Important notice:

The kit is not intended for use in neonatal screening programmes and especially not for PKU diagnosis. For this diagnostic purpose two ClinMass® LC-MS/MS Complete Kits are available.

- Easy sample preparation
- High analytical sensitivity
- Reliable monitoring



Test Data

| | |
|----------------------------|----------------|
| Linearity: | 0.2 - 50 mg/dl |
| Recovery: | 90 - 100 % |
| Lower detection limit: | 0.1 mg/dl |
| Lower determination limit: | 0.2 mg/dl |
| Intraassay precision: | Plasma: 2.9 % |
| Interassay precision: | Plasma: 4.5 % |

HPLC Parameters

| | |
|---------------------|------------------------------------------|
| Pump: | isocratic pump, flow rate: 1.0 ml/min |
| Injection volume: | 20 µl |
| Injection interval: | 12 min |
| UV/VIS-Detector: | 214 nm |
| HPLC-Thermostat: | 30 °C |

Sample Preparation

Precipitation:

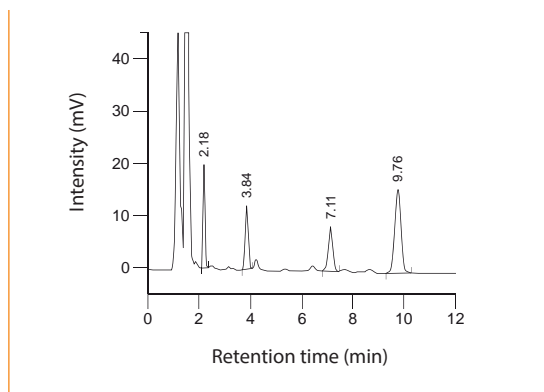
Pipette 50 µl sample into a vial with order no. 10020
(contains Precipitant P and Internal Standard)

1. incubate (15 min, 4 °C)
2. centrifuge

HPLC Analysis:

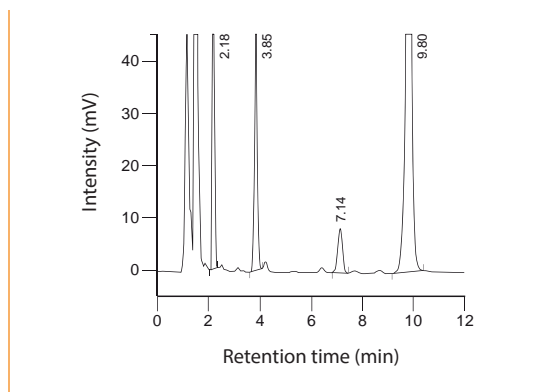
Inject 20 µl of the supernatant

ClinChek® Plasma Control, Level I



Tyrosine: 2.18 min, Phenylalanine: 3.84 min, IS: 7.11 min, Tryptophan: 9.76 min

ClinChek® Plasma Control, Level II



Tyrosine: 2.18 min, Phenylalanine: 3.85 min, IS: 7.14 min, Tryptophan: 9.80 min

Ordering Information

| Order No. | Description | Quantity |
|------------------------------------------|--------------------------------------------------------------------------------|-------------------------|
| 10000 | ClinRep® Complete Kit for Aromatic Amino Acids in Plasma for 100 assays | 1 pce. |
| Kit Components (order no.: 10000) | | |
| 10010 | Mobile Phase | 1000 ml |
| 10011 | Standard Solution | 4 ml |
| 10013 | Plasma Calibrator, lyophil. | 3 ml |
| 10020 | Sample Preparation Vials with Precipitant P and Internal Standard | 2 x 10020 (2 x 50 pcs.) |
| | Manual | 1 pce. |
| | Quick Reference | 1 pce. |
| Start Accessories: | | |
| 10030 | Analytical Column with test chromatogram | 1 pce. |
| FK7000 | manu-CART® cartridgeholder, one time accessory | 1 set |
| Accessories: | | |
| FK5810 | PEEK tubing (connection of prefilter and column) | 1 pce. |
| FK5820 | Stainless steel prefilter holder incl. 1 prefilter | 1 pce. |
| FK5821 | Replacement filter for stainless steel prefilter holder | 10 pcs. |
| ClinChek® Controls: | | |
| 10080 | Plasma Control, lyophil. Level I | 10 x 3 ml |
| 10081 | Plasma Control, lyophil. Level II | 10 x 3 ml |
| 10082 | Plasma Control, lyophil., Level I, II | 2 x 5 x 3 ml |

Homocysteine in Plasma

Homocysteine is an established marker to estimate the risk towards atherosclerosis and coronary heart disease. An elevated plasma homocysteine level (hyperhomocysteinemia), caused by nutrient deficiencies or by genetic defects, can be reduced by intake of folic acid, vitamin B6 and B12. Therefore the determination of homocysteine does not only serve for the risk assessment towards atherosclerotic affections but also to ensure the proper combination and dosage of a nutrition supplement therapy.

- Reliable sample preparation (specific derivatisation reagent)
- Injection interval: 5 min



Test Data

Linearity: 1 - 100 $\mu\text{mol/l}$
Recovery: 95 - 105 %
LOD: 0.5 $\mu\text{mol/l}$
LLOQ: 1 $\mu\text{mol/l}$
Intraassay precision: 3.9 %
Interassay precision: 5.8 %

HPLC Parameters

Pump: isocratic pump,
flow rate: 1.0 ml/min
Injection volume: 20 μl
Injection interval: 5 min
Fluorescence
detector: 385 nm (exc.), 515 nm (em.)
HPLC-Thermostat: 30 °C

Sample Preparation

Reduction:

| | | |
|-----------------------------|------------------------------------------|-------------------------------|
| 100 μl plasma | 25 μl Internal Standard IS | 25 μl Reagent A |
|-----------------------------|------------------------------------------|-------------------------------|

Precipitation:

| | |
|----------------------------------|-----------------------------|
| 150 μl reduced sample | 100 μl Reagent B |
|----------------------------------|-----------------------------|

centrifuge

Derivatisation:

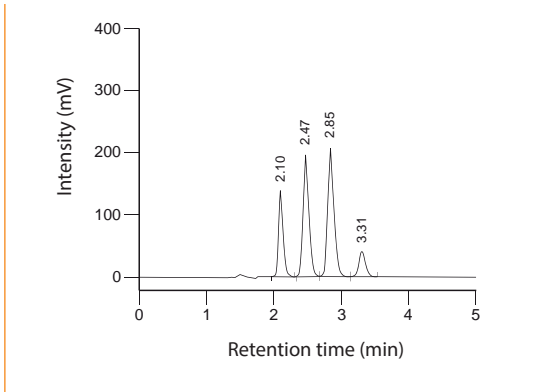
| | | |
|---------------------------------|--------------------------------|-------------------------------|
| 50 μl supernatant | 100 μl Reagent C | 50 μl Reagent D |
|---------------------------------|--------------------------------|-------------------------------|

incubate (60 min, 60 °C)

HPLC Analysis:

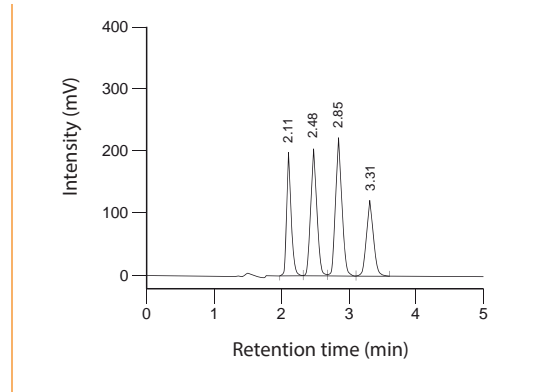
| |
|-------------------------|
| Inject 20 μl |
|-------------------------|

ClinChek® Plasma Control, Level I



Cysteine: 2.10 min, IS: 2.47 min, Cysteinylglycine: 2.85 min, Homocysteine: 3.31 min

ClinChek® Plasma Control, Level II



Cysteine: 2.11 min, IS: 2.48 min, Cysteinylglycine: 2.85 min, Homocysteine: 3.31 min

Ordering Information

| Order No. | Description | Quantity |
|------------------------------------------|------------------------------------------------------------------------|---------------|
| 23000 | ClinRep® Complete Kit for Homocysteine in Plasma for 100 assays | 1 pce. |
| Kit Components (order no. 23000): | | |
| 23010 | Mobile Phase | 1000 ml |
| 23011 | Standard Solution | 3 ml |
| 23012 | Internal Standard IS | 3 ml |
| 23013 | Plasma Calibrator, lyophil. | 3 ml |
| 23020 | Sample Preparation Vials | 100 pcs. |
| 23021 | Reagent A | 3 ml |
| 23022 | Reagent B | 10 ml |
| 23023 | Reagent C | 10 ml |
| 23024 | Reagent D | 5 ml |
| | Manual | 1 pce. |
| | Quick Reference | 1 pce. |
| Start Accessories: | | |
| 23030 | Analytical Column with test chromatogram | 1 pce. |
| Accessories: | | |
| FK5810 | PEEK tubing (connection of prefilter and column) | 1 pce. |
| FK5820 | Stainless steel prefilter holder incl. 1 prefilter | 1 pce. |
| FK5821 | Replacement filter for stainless steel prefilter holder | 10 pcs. |
| ClinChek® Controls: | | |
| 23082 | Plasma Control, lyophil., Level I, II | 2 x 5 x 3 ml |

Hydroxyproline in Urine

Osteoporosis is a metabolic bone disease which is characterised by an abnormally low bone density and therefore is associated with an increased risk of fracture. The bone degradation goes along with an increased formation of the amino acid hydroxyproline, which is released into blood circulation and is excreted with urine. The RECIPE test kit guarantees an accurate hydroxyproline measurement. Using a special sample preparation, hydroxyproline is turned into a derivative and can be quantified without interferences from other amino acids.

- High analytical selectivity
- Injection interval: 8 min
- Reliable determination



Test Data

| | |
|-----------------------|--------------|
| Linearity: | 5 - 170 mg/l |
| Recovery: | 90 - 100 % |
| LOD: | 3 mg/l |
| LLOQ: | 5 mg/l |
| Intraassay precision: | 3.5 % |
| Interassay precision: | 4.5 % |

HPLC Parameters

| | |
|---------------------|------------------------------------------------------|
| Pump: | binary gradient pump, flow rates: 1.2, 1.4 ml/min |
| Injection volume: | 20 µl |
| Injection interval: | 8 min |
| UV/VIS-Detector: | 471 nm |
| HPLC-Thermostat: | 60 °C |

Sample Preparation

Hydrolysis:

| | | |
|------------|-----------------------------|----------|
| 1 ml urine | 100 µl Internal Standard IS | 1 ml HCl |
|------------|-----------------------------|----------|

incubate (16 h, 95 °C)

Derivatisation:

1. 100 µl sample + 300 µl Reagent A + 800 µl Reagent B / C
2. 500 µl sample + 200 µl Reagent D
3. 150 µl sample + 200 µl Reagent E

incubate (10 min, 70 °C)

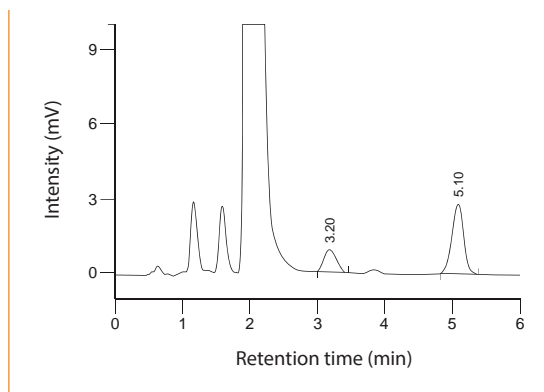
Dilution:

| | |
|-----------------|-----------------------|
| Complete sample | 500 µl Mobile Phase A |
|-----------------|-----------------------|

HPLC Analysis:

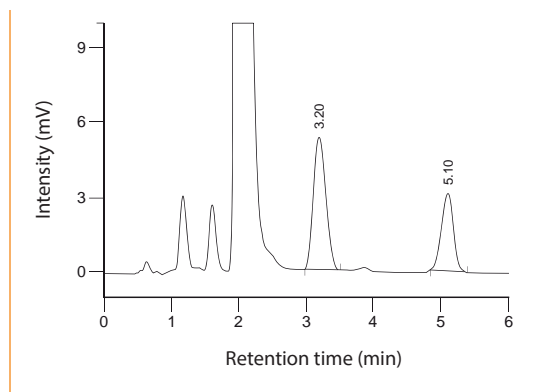
| |
|--------------|
| Inject 20 µl |
|--------------|

ClinChek® Urine Control, Level I



Hydroxyproline: 3.20 min, IS: 5.10 min

ClinChek® Urine Control, Level II



Hydroxyproline: 3.20 min, IS: 5.10 min

Ordering Information

| Order No. | Description | Quantity |
|-----------------------------------------|------------------------------------------------------------------|-----------------------|
| 16000 | ClinRep® Complete Kit for Hydroxyproline in Urine for 100 assays | 1 pce. |
| Kit Components (order no 16000): | | |
| 16008 | Mobile Phase A | 1000 ml |
| 16009 | Mobile Phase B | 150 ml |
| 16011 | Standard Solution | 5 ml |
| 16012 | Internal Standard IS | 10 ml |
| 16013 | Urine Calibrator, lyophil. | 5 x 8 ml |
| 16020 | Hydrolysis Tubes with Caps | 100 pcs. |
| 16021 | pH - Test Stripes | 100 pcs. |
| 16022 | Reagent A | 30 ml |
| 16023 | Reagent B | 80 ml |
| 16024 | Reagent C | 80 ml |
| 16025 | Reagent D | 2 x 16025 (2 x 50 mg) |
| 16026 | Reagent E | 20 ml |
| | Manual | 1 pce. |
| | Quick Reference | 1 pce. |
| Start Accessories: | | |
| 16030 | Analytical Column with test chromatogram | 1 pce. |
| Accessories: | | |
| FK5810 | PEEK tubing (connection of prefilter and column) | 1 pce. |
| FK5820 | Stainless steel prefilter holder incl. 1 prefilter | 1 pce. |
| FK5821 | Replacement filter for stainless steel prefilter holder | 10 pcs. |
| ClinChek® Controls: | | |
| 8820 | Urine Control, lyophil., Level I | 10 x 8 ml |
| 8821 | Urine Control, lyophil., Level II | 10 x 8 ml |
| 8822 | Urine Control, lyophil., Level I, II | 2 x 5 x 8 ml |

Porphyryns Differentiated in Urine

The porphyrin excretion profile is used for the diagnosis of porphyrias. This ClinRep® Complete Kit allows the separation (differentiation) of the urinary porphyrins with high resolution (in different porphyrin-isomers!) and ensures an exact quantification. For sample preparation the samples simply have to be spiked with an internal standard and centrifuged.

- High resolution of the porphyrin profile
- No interferences
- High analytical sensitivity



Test Data

| | |
|-----------------------|---------------|
| Linearity: | 1 - 5000 µg/l |
| LOD: | 0.5 µg/l |
| LLOQ: | 1 µg/l |
| Intraassay precision: | 2.3 % |
| Interassay precision: | 2.6 % |

HPLC Parameters

| | |
|---------------------------|------------------------------------------------|
| Pump: | binary gradient pump, flow rate: 0.7 ml/min |
| Injection volume: | 20 µl |
| Injection interval: | 20 min |
| Fluorescence detector: | 394 nm (exc.), 624 nm (em.) |
| HPLC-Thermostat: | 30 °C |

Sample Preparation

Addition of IS:

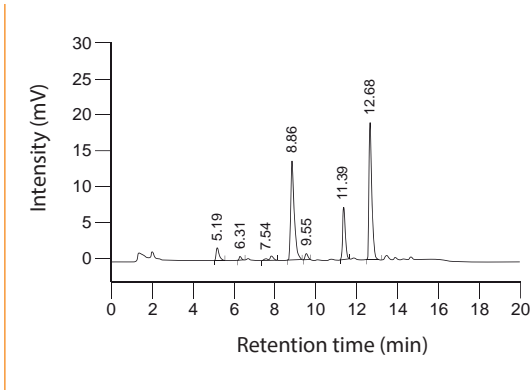
| | |
|------------------------------------------------|-------------------------------|
| 500 µl urine (calibrator, control, patient) | 50 µl Internal Standard IS |
|------------------------------------------------|-------------------------------|

centrifuge

HPLC Analysis:

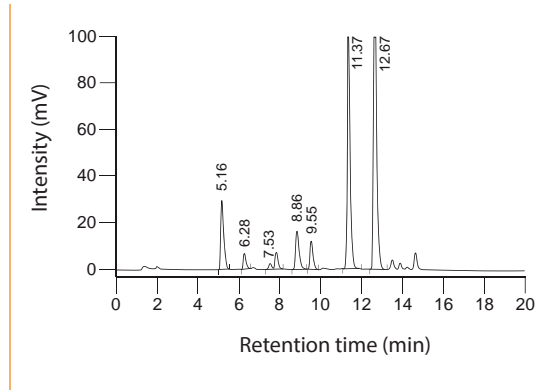
Inject 20 µl of the supernatant

ClinChek® Urine Control, Level I



Uroporphyrin I: 5.19 min, Heptacarboxyporphyrin I: 6.31 min, Hexacarboxyporphyrins (Iac and lab Isomer): 7.54 min, Internal Standard IS: 8.86 min, Pentacarboxyporphyrin I: 9.55 min, Coproporphyrin I: 11.39 min, Coproporphyrin III: 12.68 min

ClinChek® Urine Control, Level II



Uroporphyrin I: 5.16 min, Heptacarboxyporphyrin I: 6.28 min, Hexacarboxyporphyrins (Iac and lab Isomer): 7.53 min, Internal Standard IS: 8.86 min, Pentacarboxyporphyrin I: 9.55 min, Coproporphyrin I: 11.37 min, Coproporphyrin III: 12.67 min

Ordering Information

| Order No. | Description | Quantity |
|------------------------------------------|---------------------------------------------------------------------|-------------------------|
| 17000 | ClinRep® Complete Kit for Porphyrins in Urine for 100 assays | 1 pce. |
| Kit Components (order no. 17000): | | |
| 17008 | Mobile Phase A | 2 x 17008 (2 x 1000 ml) |
| 17009 | Mobile Phase B | 800 ml |
| 17011 | Standard Solution | 5 ml |
| 17012 | Internal Standard IS | 5 ml |
| 17013 | Urine Calibrator, lyophil. | 5 x 5 ml |
| 17020 | Vials for Sample Pretreatment | 100 pcs. |
| | Manual | 1 pce. |
| | Quick Reference | 1 pce. |
| Start Accessories: | | |
| 17030 | Analytical Column with test chromatogram | 1 pce. |
| 17032 | Guard Column Holder incl. 1 Guard Column | 1 pce. |
| 17033 | Guard Column | 5 pcs. |
| Accessories: | | |
| FK5810 | PEEK tubing (connection of prefilter and column) | 1 pce. |
| FK5820 | Stainless steel prefilter holder incl. 1 prefilter | 1 pce. |
| FK5821 | Replacement filter for stainless steel prefilter holder | 10 pcs. |
| ClinChek® Controls: | | |
| 17080 | Urine Control, lyophil., Level I | 10 x 5 ml |
| 17081 | Urine Control, lyophil., Level II | 10 x 5 ml |
| 17082 | Urine Control, lyophil., Level I, II | 2 x 5 x 5 ml |

1.1.5. Oxidative Stress

β -Carotene in Plasma / Serum

β -Carotene belongs to the group of the so-called carotenoids. These compounds are part of the antioxidant defense system within the human organism and are protecting cells and tissues from oxidative damage (oxidative stress). All-trans- β -carotene is the quantitatively most important carotenoid in our diet, in human blood and tissues. The RECIPE ClinRep® Complete Kit for β -carotene provides a unique chromatographical performance. Even the cis-isomers of β -carotene (9-cis- β -carotene, 13-cis- β -carotene) are baseline-separated. Prior to HPLC analysis a simple two-step sample preparation (precipitation, stabilisation) is required.

- Short time sample preparation (only 2 steps)
- Excellent chromatographic performance (separation of cis-isomers)
- Injection interval: 10 min

Test Data

Test data are available on request.

HPLC Parameters

Pump: isocratic pump,
flow rate: 1.1 ml/min
Injection volume: 100 μ l
Injection interval: 10 min
UV-Detector: 450 nm
HPLC-Thermostat: 30 °C

Sample Preparation

Precipitation:

| | | |
|--------------------|--------------------------------------------|--------------------------------------|
| 100 μ l sample | 200 μ l Precipitant P (contains IS) | 100 μ l Stabilising Reagent S |
|--------------------|--------------------------------------------|--------------------------------------|

mix, centrifuge

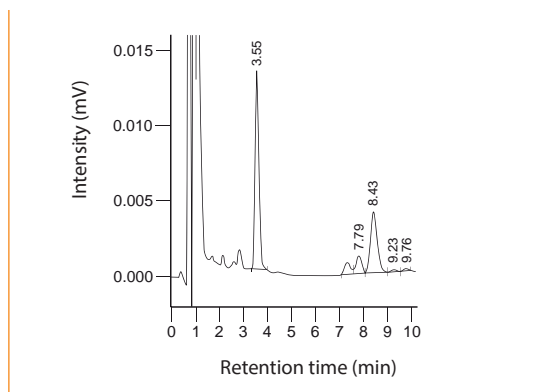
HPLC Analysis:

Inject 100 μ l



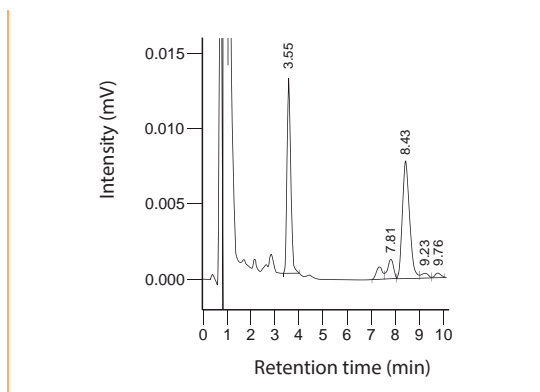
1.1.5. Oxidative Stress

ClinChek® Plasma Control, Level I



IS: 3.55 min, α -Carotene: 7.79 min, all-trans- β -Carotene: 8.43 min, 9-cis- β -Carotene: 9.23 min, 13-cis- β -Carotene: 9.76 min

ClinChek® Plasma Control, Level II



IS: 3.55 min, α -Carotene: 7.81 min, all-trans- β -Carotene: 8.43 min, 9-cis- β -Carotene: 9.23 min, 13-cis- β -Carotene: 9.76 min

Ordering Information

| Order No. | Description | Quantity |
|------------------------------------------|-----------------------------------------------------------------------------------------------|---------------|
| 30000 | ClinRep® Complete Kit for β-Carotene in Plasma / Serum for 100 assays | 1 pce. |
| Kit Components (order no. 30000): | | |
| 30010 | Mobile Phase | 1000 ml |
| 30012 | Precipitant P with Internal Standard | 4 x 5 ml |
| 30013 | Plasma Calibrator, lyophil. | 5 x 0.5 ml |
| 30014 | Test Solution, lyophil. | 3 ml |
| 30015 | Reconstitution Solution R | 20 ml |
| 30020 | Sample Preparation Vials | 100 pcs. |
| 30021 | Stabilising Reagent S | 10 ml |
| | Manual | 1 pce. |
| | Quick Reference | 1 pce. |
| Start Accessories: | | |
| 30030 | Analytical Column with test chromatogram | 1 pce. |
| Accessories: | | |
| FK5810 | PEEK tubing (connection of prefilter and column) | 1 pce. |
| FK5820 | Stainless steel prefilter holder incl. 1 prefilter | 1 pce. |
| FK5821 | Replacement filter for stainless steel prefilter holder | 10 pcs. |
| ClinChek® Controls: | | |
| 30082 | Plasma Control, lyophil., Level I, II | 2 x 5 x 2 ml |

1.1.5. Oxidative Stress

Coenzyme Q10 in Whole Blood / Plasma / Serum

Coenzyme Q10 (CoQ10) plays an outstanding role in the energy production within the cell metabolism. In addition, CoQ10 is an important antioxidant and thus protects the cell from radical oxidation (oxidative stress). Low blood concentration of CoQ10 seem to cause cardiovascular diseases. The RECIPE ClinRep® Complete Kit allows a reliable determination of CoQ10 in whole blood, plasma and serum. After a quick sample preparation, the analytical chromatography is performed with an isocratic HPLC system and UV detection. For quality assurance reference materials (ClinCal® Plasma Calibrator and ClinChek® Plasma Controls) with excellent stability are available.

- Reliable sample preparation
- Reference materials with excellent stability available



Test Data

| | |
|-----------------------|-------------------|
| Linearity: | 38.9 - 20000 µg/l |
| Recovery: | 94 - 108 % |
| LOD: | 19.5 µg/l |
| LLOQ: | 38.9 µg/l |
| Intraassay precision: | 3.4 % |
| Interassay precision: | 5.0 % |

HPLC Parameters

| | |
|---------------------|------------------------------------------|
| Pump: | isocratic pump, flow rate: 1.4 ml/min |
| Injection volume: | 30 µl |
| Injection interval: | 14 min |
| UV-Detector: | 275 nm |
| HPLC-Thermostat: | 30 °C |

Sample Preparation

Precipitation:

500 µl Precipitant P

1. Add 400 µl sample
2. Add 50 µl Oxidation Reagent O

mix

Add 400 µl Internal Standard IS

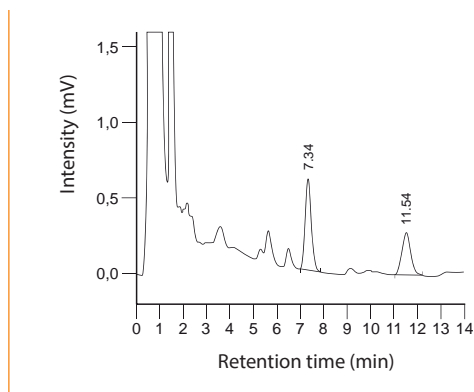
mix, centrifuge

HPLC Analysis:

Inject 30 µl of the supernatant

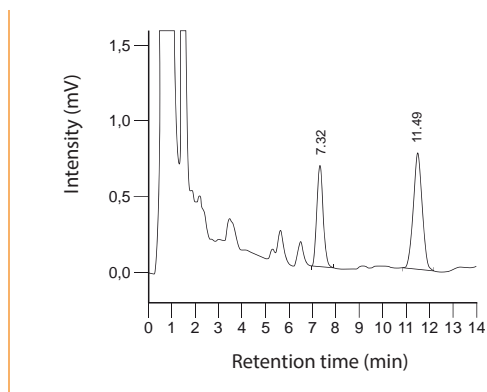
1.1.5. Oxidative Stress

ClinChek® Plasma Control, Level I



IS: 7.34 min, CoQ10: 11.54 min

ClinChek® Plasma Control, Level II



IS: 7.32 min, CoQ10: 11.49 min

Ordering Information

| Order No. | Description | Quantity |
|------------------------------------------|----------------------------------------------------------------------------------------------|---------------|
| 31000 | ClinRep® Complete Kit for Coenzyme Q10 in Whole Blood / Plasma / Serum for 100 assays | 1 pce. |
| Kit Components (order no. 31000): | | |
| 31010 | Mobile Phase | 1000 ml |
| 31012 | Internal Standard IS | 40 ml |
| 31013 | Plasma Calibrator, lyophil. | 5 x 2 ml |
| 31014 | Test Solution | 3 ml |
| 31020 | Sample Preparation Vials | 100 pcs. |
| 31021 | Precipitant P | 50 ml |
| 31022 | Oxidation Reagent O | 5 ml |
| | Manual | 1 pce. |
| | Quick Reference | 1 pce. |
| Start Accessories: | | |
| 31030 | Analytical Column with test chromatogram | 1 pce. |
| 31032 | Guard Column Holder incl. 1 Guard Column | 1 pce. |
| Accessories: | | |
| 31033 | Guard Column | 5 pcs. |
| FK5810 | PEEK tubing (connection of prefilter and column) | 1 pce. |
| FK5820 | Stainless steel prefilter holder incl. 1 prefilter | 1 pce. |
| FK5821 | Replacement filter for stainless steel prefilter holder | 10 pcs. |
| ClinChek® Controls: | | |
| 31082 | Plasma Control, lyophil., Level I, II | 2 x 5 x 2 ml |

1.1.5. Oxidative Stress

Malondialdehyde in Plasma / Serum

Malondialdehyde is formed by radical mediated lipid peroxidation (oxidative stress) and shows mutagenic and cytotoxic effects by further reaction with DNA. For this reason malondialdehyde is considered a suitable biomarker for the determination of oxidative stress. The RECIPE ClinRep® Complete Kit allows the reliable quantification of malondialdehyde from plasma and serum. For quality assurance a ClinCal® Plasma Calibrator and ClinChek® Plasma Controls in two levels are available.

- Reliable sample preparation
- Robust chromatography
- Injection interval: 5 min

Test Data

| | |
|-----------------------|------------------|
| Linearity: | 0.04 - 20 µmol/l |
| Recovery: | 100 % |
| LOD: | 0.02 µmol/l |
| LLOQ: | 0.04 µmol/l |
| Intraassay precision: | 3.7 % |
| Interassay precision: | 7.4 % |

HPLC Parameters

| | |
|---------------------------|------------------------------------------|
| Pump: | isocratic pump, flow rate: 0.8 ml/min |
| Injection volume: | 20 µl |
| Injection interval: | 5 min |
| Fluorescence detector: | 515 nm (exc.), 553 nm (em.) |
| HPLC-Thermostat: | 30 °C |

Sample Preparation

Derivatisation:

| | | |
|------------------|---------------------|---------------------|
| 100 µl sample | 700 µl Reagent A | 200 µl Reagent B |
|------------------|---------------------|---------------------|

incubate (60 min, 100 °C)

Neutralisation / Precipitation:

| | |
|------------------|---------------------|
| 200 µl sample | 200 µl Reagent C |
|------------------|---------------------|

centrifuge

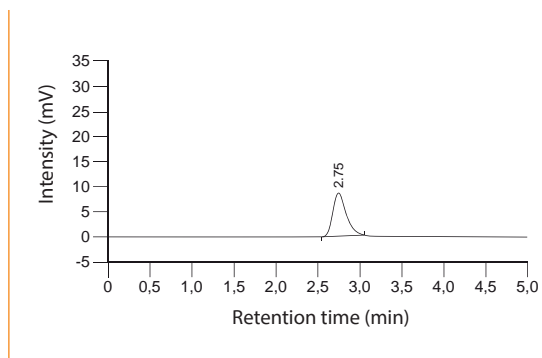
HPLC Analysis:

Inject 20 µl of the supernatant



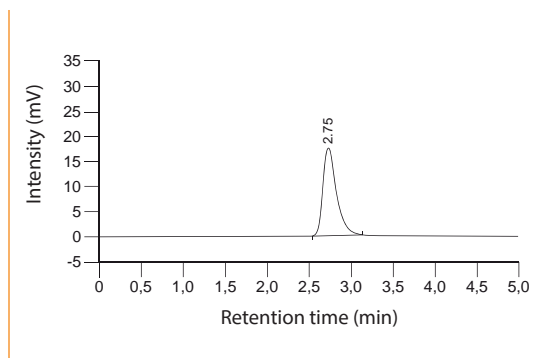
1.1.5. Oxidative Stress

ClinChek® Plasma Control, Level I



Malondialdehyde: 2.75 min

ClinChek® Plasma Control, Level II



Malondialdehyde: 2.75 min

Ordering Information

| Order No. | Description | Quantity |
|------------------------------------------|-----------------------------------------------------------------------------------|----------------|
| 32000 | ClinRep® Complete Kit for Malondialdehyde in Plasma / Serum for 100 assays | 1 pce. |
| Kit Components (order no. 32000): | | |
| 32010 | Mobile Phase | 1000 ml |
| 32013 | Plasma Calibrator, lyophil. | 5 x 0.5 ml |
| 32020 | Derivatisation Vials | 100 pcs. |
| 32021 | Sample Preparation Vials | 100 pcs. |
| 32022 | Reagent A | 70 ml |
| 32023 | Reagent B | 20 ml |
| 32024 | Reagent C | 20 ml |
| | Manual | 1 pce. |
| | Quick Reference | 1 pce. |
| Start Accessories: | | |
| 32030 | Analytical Column with test chromatogram | 1 pce. |
| 32031 | Guard Columns | 5 pcs. |
| FK7000 | manu-CART® cartridgeholder, one time accessory | 1 set |
| Accessories: | | |
| FK5810 | PEEK tubing (connection of prefilter and column) | 1 pce. |
| FK5820 | Stainless steel prefilter holder incl. 1 prefilter | 1 pce. |
| FK5821 | Replacement filter for stainless steel prefilter holder | 10 pcs. |
| ClinChek® Controls: | | |
| 32082 | Plasma Control, lyophil., Level I, II | 2 x 5 x 0.5 ml |

1.1.5. Oxidative Stress

Vitamin C in Plasma

Vitamin C (ascorbic acid) is a potential scavenger to radicals and oxidants. The exposure to these species is termed as "oxidative stress". Oxidative stress is believed to contribute to the development of various chronic diseases such as cardiovascular disease, diabetes and cancer. An inadequate vitamin C status is usually observed in cases of malnutrition, smoking, alcohol abuse, chronic toxications and stress. Nursing women and elderly people are also in danger of a low vitamin C status. The RECIPE test kit features fast analysis (quick sample preparation, short run time) and ensures reliable results.

- Quick sample preparation
- Injection interval: 5 min



Test Data

| | |
|-----------------------|----------------|
| Linearity: | 0.5 - 300 mg/l |
| Recovery: | 95 - 100 % |
| LOD: | 0.1 mg/l |
| LLOQ: | 0.5 mg/l |
| Intraassay precision: | 5.9 % |
| Interassay precision: | 6.9 % |

HPLC Parameters

| | |
|---------------------|------------------------------------------|
| Pump: | isocratic pump, flow rate: 1.3 ml/min |
| Injection volume: | 20 µl |
| Injection interval: | 5 min |
| UV-Detector: | 243 nm |
| HPLC-Thermostat: | 30 °C |

Sample Preparation

Precipitation:

| | |
|------------------|---------------------------------------------------------|
| 100 µl sample | 100 µl Precipitant P (contains Internal Standard IS) |
|------------------|---------------------------------------------------------|

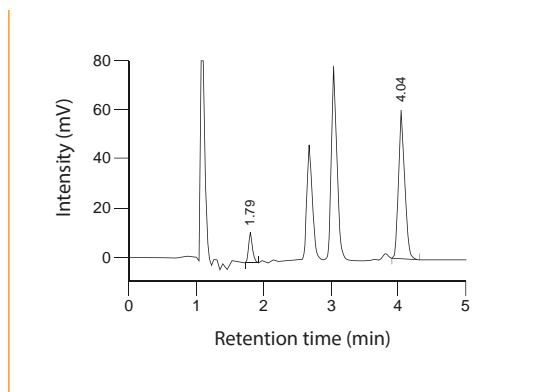
1. incubate (10 min, + 4°C)
2. centrifuge

HPLC Analysis:

Inject 20 µl of the supernatant

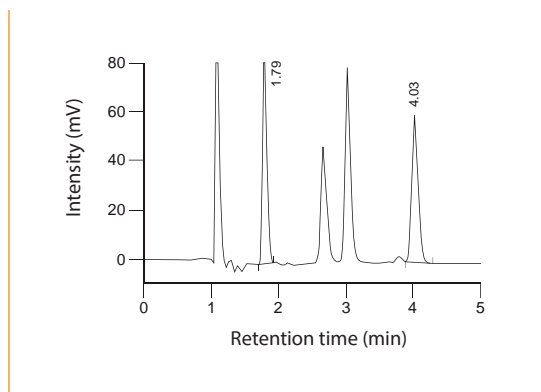
1.1.5. Oxidative Stress

ClinChek® Serum Control, Level I



Vitamin C: 1.79 min, IS: 4.04 min

ClinChek® Serum Control, Level II



Vitamin C: 1.79 min, IS: 4.03 min

Ordering Information

| Order No. | Description | Quantity |
|------------------------------------------|---------------------------------------------------------------------|----------------|
| 28000 | ClinRep® Complete Kit for Vitamin C in Plasma for 100 assays | 1 pce. |
| Kit Components (order no. 28000): | | |
| 28010 | Mobile Phase | 1000 ml |
| 28012 | Precipitant P with Internal Standard, lyophil. | 5 x 3 ml |
| 28013 | Serum Calibrator, lyophil. | 5 x 0.5 ml |
| 28014 | Test Solution, lyophil. | 5 x 1 ml |
| 28015 | Reconstitution Solution R | 25 ml |
| 28020 | Sample Preparation Vials | 100 pcs. |
| | Manual | 1 pce. |
| | Quick Reference | 1 pce. |
| Start Accessories: | | |
| 28030 | Analytical Column with test chromatogram | 1 pce. |
| 28032 | Guard Column Holder incl. 1 Guard Column | 1 pce. |
| Accessories: | | |
| 28033 | Guard Columns | 5 pcs. |
| FK5810 | PEEK tubing (connection of prefilter and column) | 1 pce. |
| FK5820 | Stainless steel prefilter holder incl. 1 prefilter | 1 pce. |
| FK5821 | Replacement filter for stainless steel prefilter holder | 10 pcs. |
| ClinChek® Controls: | | |
| 28082 | Serum Control, lyophil., Level I, II | 2 x 5 x 0.5 ml |

1.1.6. Vitamin Status

Vitamin A and E in Serum / Plasma

Vitamin A (retinol) and vitamin E (α -tocopherol) belong to the fat soluble class of vitamins. In contrast to water soluble vitamins, an excessive administration may lead to hypervitaminosis. Vitamin A deficiency is the leading cause of preventable blindness in children and raises the risk of disease and death from severe infections. Vitamin E is an important antioxidant and is thought to have a role in preventing atherosclerosis by inhibiting oxidation of low density lipoprotein (LDL). The RECIPE ClinRep® Complete Kit allows for the simultaneous analysis of both vitamins within a run time of 8 min. For quality assurance, reference materials with excellent stability are available.

- Fast sample preparation
- Injection interval: 8 min
- Reference materials with excellent stability



Test Data

| | |
|-----------------------|----------------------------------------------------------|
| Linearity: | Vitamin A: 0.02 - 5.0 mg/l, Vitamin E: 0.40 - 50 mg/l |
| Recovery: | 92 - 98 % |
| LOD: | Vitamin A: 0.01 mg/l, Vitamin E: 0.30 mg/l |
| LLOQ: | Vitamin A: 0.02 mg/l, Vitamin E: 0.40 mg/l |
| Intraassay precision: | Vitamin A: 1.4 %, Vitamin E: 1.4 % |
| Interassay precision: | Vitamin A: 5.0 %, Vitamin E: 3.2 % |

HPLC Parameters

| | |
|---------------------|------------------------------------------|
| Pump: | isocratic pump, flow rate: 1.5 ml/min |
| Injection volume: | 50 μ l |
| Injection interval: | 8 min |
| UV-Detector: | 325 / 295 nm |
| HPLC-Thermostat: | 30 °C |

Sample Preparation

Extraction:

| | |
|-------------------------------|--------------------------------------------------------------|
| 150 μ l plasma / serum | 150 μ l Precipitant P (contains Internal Standard IS) |
|-------------------------------|--------------------------------------------------------------|

centrifuge

Stabilisation:

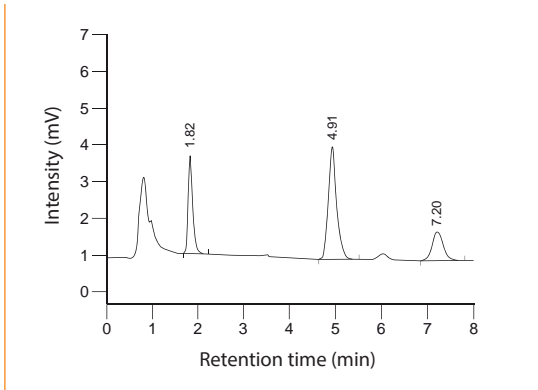
| | |
|----------------------------|--------------------------------------|
| 100 μ l supernatant | 100 μ l Stabilising Reagent S |
|----------------------------|--------------------------------------|

centrifuge

HPLC Analysis:

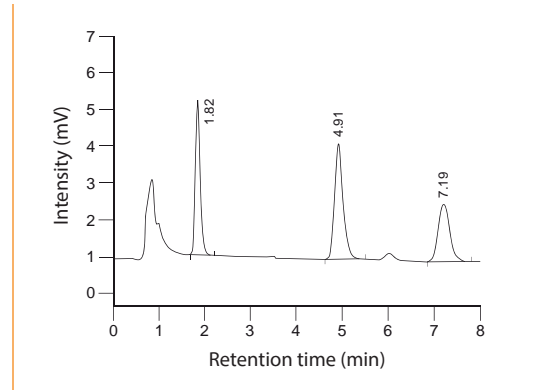
Inject 50 μ l of the supernatant

ClinChek® Serum Control, Level I



Vitamin A: 1.82 min, IS: 4.91 min, Vitamin E: 7.20 min

ClinChek® Serum Control, Level II



Vitamin A: 1.82 min, IS: 4.91 min, Vitamin E: 7.19 min

Ordering Information

| Order No. | Description | Quantity |
|------------------------------------------|-----------------------------------------------------------------------------------|-------------------------|
| 22000 | ClinRep® Complete Kit for Vitamin A and E in Serum / Plasma for 100 assays | 1 pce. |
| Kit components (order no. 22000): | | |
| 22010 | Mobile Phase | 1000 ml |
| 22011 | Standard Solution | 3 ml |
| 22012 | Precipitant P with Internal Standard | 15 ml |
| 22013 | Serum Calibrator, lyophil. | 3 ml |
| 22020 | Sample Preparation Vials with Reagent, lyophil. | 2 x 22020 (2 x 50 pcs.) |
| 22021 | Reaction Vials | 100 pcs. |
| 22022 | Stabilising Reagent S | 10 ml |
| | Manual | 1 pce. |
| | Quick Reference | 1 pce. |
| Start Accessories: | | |
| 22030 | Analytical Column with test chromatogram | 1 pce. |
| FK7000 | manu-CART® cartridgeholder, one time accessory | 1 set |
| Accessories: | | |
| FK5810 | PEEK tubing (connection of prefilter and column) | 1 pce. |
| FK5820 | Stainless steel prefilter holder incl. 1 prefilter | 1 pce. |
| FK5821 | Replacement filter for stainless steel prefilter holder | 10 pcs. |
| ClinChek® Controls: | | |
| 8870 | Serum Control, lyophil., Level I | 10 x 5 ml |
| 8871 | Serum Control, lyophil., Level II | 10 x 5 ml |
| 8872 | Serum Control, lyophil., Level III | 10 x 5 ml |
| 8873 | Serum Control, lyophil., Level I, II, III | 3 x 3 x 5 ml |

1.1.6. Vitamin Status

Vitamin A and E in Serum / Plasma by UHPLC

Vitamin A (Retinol) und vitamin E (Tocopherol) belong to the fat soluble class of vitamins. In contrast to the water soluble an excessive administration may lead to hypervitaminosis. Vitamin A deficiency is the leading cause of preventable blindness in children and raises the risk of disease and death from severe infections. Vitamin E is an important antioxidant and is thought to have a role in preventing atherosclerosis by inhibiting oxidation of LDL. This ClinRep® Complete Kit is designed for analysis on UHPLC systems. RECIPE's analytical method enables a high sample throughput by combining fast chromatography (1.2 min injection interval) and fast sample preparation (one step matrix precipitation). The analysis can be performed from serum or plasma. For quality assurance, reference materials with excellent stability are available.

- Fast and simple
- Injection interval: 1.2 min



Test Data

| | |
|-------------|-----------------------------------------------------------|
| Linearity: | Vitamin A: 0.04 - 3.96 mg/L Vitamin E: 1.02 - 104 mg/L |
| Recovery: | 96 - 109% |
| LOD: | Vitamin A: 0.013 mg/L Vitamin E: 0.535 mg/L |
| LLOQ: | Vitamin A: 0.04 mg/L Vitamin E: 1.07 mg/L |
| Intraassay: | Vitamin A: 1.7 – 7.1% Vitamin E: 1.4 – 4.0% |
| Interassay: | Vitamin A: 1.9 – 3.2% Vitamin E: 1.4 – 2.3% |

UHPLC Parameters

| | |
|---------------------|------------------------------------------|
| Pump: | isocratic pump, flow rate: 0.8 ml/min |
| Injection volume: | 5 µl |
| Injection interval: | 1.2 min |
| UV-Detector: | 325 / 295 nm |
| Column heater: | 30 °C |

Sample Preparation

Precipitation

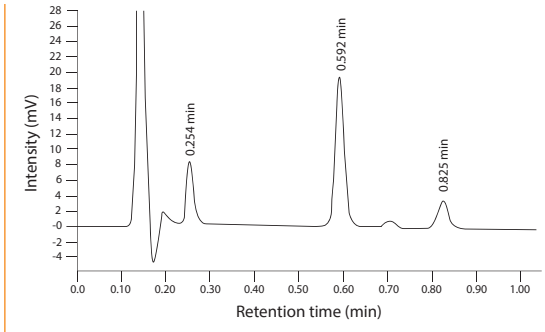
| | | |
|----------------------|------------------------------------------------------|-----------------------------|
| 50 µl plasma / serum | 100 µl Precipitant P (contains Internal Standard IS) | 50 µl Stabilising Reagent S |
|----------------------|------------------------------------------------------|-----------------------------|

mix and centrifuge

UHPLC Analysis

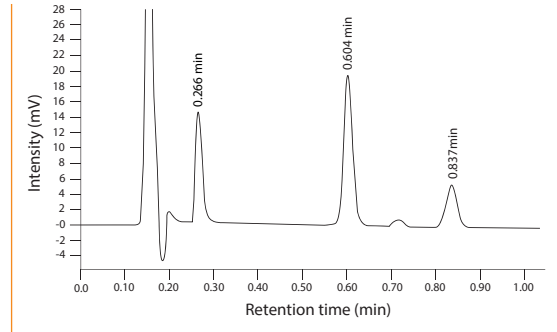
Inject 5 µl of the supernatant

ClinChek® Serum Control, Level I



Vitamin A: 0.254 min, IS: 0.592 min, Vitamin E: 0.825 min

ClinChek® Serum Control, Level II



Vitamin A: 0.266 min, IS: 0.604 min, Vitamin E: 0.837 min

Ordering Information

| Order No. | Description | Quantity |
|------------------------------------------|--------------------------------------------------------------------------------------------|---------------|
| 22100 | ClinRep® Complete Kit for Vitamin A and E in Serum / Plasma by UHPLC for 100 assays | 1 pce. |
| Kit Components (order no. 22100): | | |
| 22010 | Mobile Phase | 1000 ml |
| 22011 | Standard Solution | 3 ml |
| 22112 | Precipitant P with Internal Standard | 10 ml |
| 22013 | Serum Calibrator, lyophil. | 3 ml |
| 22120 | Sample Preparation Vials | 100 pcs. |
| 22121 | Stabilising Reagent S | 5 ml |
| | Manual | 1 pce. |
| | Quick Reference | 1 pce. |
| Separately available components: | | |
| 22010 | Mobile Phase | 1000 ml |
| 22011 | Standard Solution | 3 ml |
| 22112 | Precipitant P with Internal Standard | 10 ml |
| 22013 | Serum Calibrator, lyophil. | 3 ml |
| 22120 | Sample Preparation Vials | 100 pcs. |
| 22121 | Stabilising Reagent S | 5 ml |
| Start Accessories: | | |
| 22130 | Analytical Column with test chromatogram | 1 pce. |
| ClinChek® Controls: | | |
| 8870 | Serum Control, lyophil., Level I | 10 x 5 ml |
| 8871 | Serum Control, lyophil., Level II | 10 x 5 ml |
| 8872 | Serum Control, lyophil., Level III | 10 x 5 ml |
| 8873 | Serum Control, lyophil., Level I, II, III | 3 x 3 x 5 ml |

1.1.6. Vitamin Status

Vitamin B1 in Whole Blood

Vitamin B1 (thiamine, thiamine pyrophosphate (TPP)) acts as coenzyme in the carbohydrate metabolism and is essential for the normal functioning of the organism. Deficiency mainly occurs in undernourished people, alcoholics or in special clinical situations (e.g. hemodialysis). A fully developed deficiency syndrome is called "Beriberi". With this RECIPE test kit, vitamin B1 is determined as TPP. The kit can be combined in a convenient manner with the test kits for vitamin B2 and B6 (see combi kit).

- Excellent sensitivity: 0.5 µg/l
- Injection interval: 6 min
- Chromatography combinable with B2 and B6 test kits



Test Data Determination as TPP

| | |
|-----------------------|--------------|
| Linearity: | 1 - 200 µg/l |
| Recovery: | 95 - 100 % |
| LOD: | 0.5 µg/l |
| LLOQ: | 1 µg/l |
| Intraassay precision: | 2.7 % |
| Interassay precision: | 4.2 % |

HPLC Parameters

| | |
|---------------------------|------------------------------------------|
| Pump: | isocratic pump, flow rate: 1.0 ml/min |
| Pump (Reagent N): | flow rate: 0.1 ml/min |
| Injection volume: | 50 µl |
| Injection interval: | 6 min |
| Fluorescence detector: | 376 nm (exc.), 435 nm (em.) |
| HPLC-Thermostat: | 35 °C |

Sample Preparation

Extraction:

| | |
|-----------------------|---------------------|
| 300 µl whole blood | 500 µl Reagent A |
|-----------------------|---------------------|

1. centrifuge
2. take off 400 µl supernatant

Stabilisation:

Add 50 µl Reagent S

Oxidation:

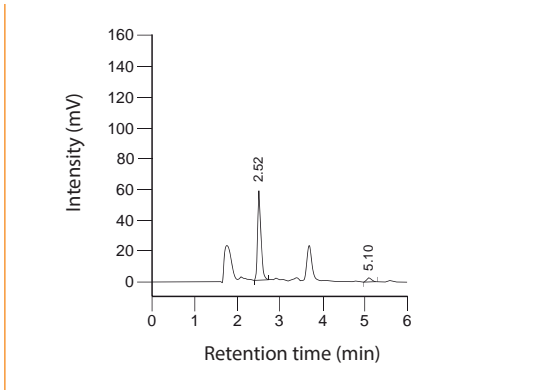
| | | |
|---------------|-----------------|------------------|
| 450 µl sample | 50 µl Reagent C | 100 µl Reagent D |
|---------------|-----------------|------------------|

add 100 µl Reagent E

HPLC Analysis:

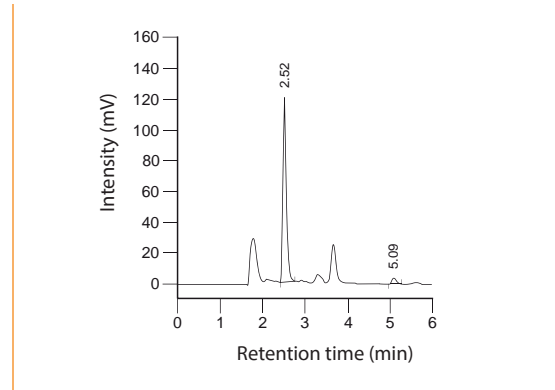
Inject 50 µl of the supernatant

ClinChek® Whole Blood Control, Level I



TPP: 2.52 min, Thiamine: 5.10 min

ClinChek® Whole Blood Control, Level II



TPP: 2.52 min, Thiamine: 5.09 min

Ordering Information

| Order No. | Description | Quantity |
|------------------------------------------|--------------------------------------------------------------------|--------------------------|
| 24000 | ClinRep® Complete Kit for Vitamin B1 in Whole Blood for 100 assays | 1 pce. |
| Kit Components (order no. 24000): | | |
| 24010 | Mobile Phase | 1000 ml |
| 24014 | Test Solution | 3 ml |
| 24513 | Whole Blood Calibrator, lyophil. | 5 x 2 ml |
| 24020 | Sample Preparation Vials | 2 x 24020 (2 x 100 pcs.) |
| 24021 | Reagent A | 50 ml |
| 24023 | Reagent C | 5 ml |
| 24024 | Reagent D | 10 ml |
| 24025 | Reagent E | 10 ml |
| 24626 | Reagent N | 250 ml |
| 24027 | Reagent S | 5 ml |
| | Manual | 1 pce. |
| | Quick Reference | 1 pce. |
| Start Accessories: | | |
| 27030 | Analytical Column with test chromatogram | 1 pce. |
| 27032 | Guard Column Holder incl. 1 Guard Column | 1 pce. |
| Accessories: | | |
| 27033 | Guard Columns | 5 pcs. |
| FK2000 | Peristaltic pump (flow rate 0.2 ml/min) | 1 pce. |
| FK2001 | Replacement tubings for peristaltic pump | 2 pcs. |
| FK5121 | T-Union (PEEK), 1/16" | 1 pce. |
| FK5810 | PEEK-tubing (connection of prefilter and column) | 1 pce. |
| FK5820 | Stainless steel prefilter holder incl. 1 prefilter | 1 pce. |
| FK5821 | Replacement filter for stainless steel prefilter holder | 10 pcs. |
| ClinChek® Controls: | | |
| 8874 | Whole Blood Control, lyophil., Level I | 10 x 2 ml |
| 8875 | Whole Blood Control, lyophil., Level II | 10 x 2 ml |
| 8876 | Whole Blood Control, lyophil., Level I, II | 2 x 5 x 2 ml |

1.1.6. Vitamin Status

Vitamin B2 in Whole Blood

The term "vitamin B2" covers three vitamers: riboflavin, flavin mononucleotide (FMN) and flavin adenine dinucleotide (FAD). FMN and FAD are the effective forms of vitamin B2 and are synthesised in vivo from riboflavin by phosphorylation. Vitamin B2 is important for energy production and enzyme functions as well as for the fatty acid and amino acid synthesis. The undersupply with vitamin B2 is mostly attributed to a general malnutrition. It is often seen in persons with risk factors such as alcohol problems, advanced age and extreme dietary habits. The RECIPE test kit offers a short analysis time (easy sample preparation, short run time) and can be easily combined with test kits for the vitamins B1 and B6 (see combi kit).

- Quick sample preparation
- Injection interval: 10 min
- Chromatography combinable with B1 and B6 test kits



Test Data Determination as FAD

| | |
|-----------------------|---------------|
| Linearity: | 20 - 500 µg/l |
| Recovery: | 95 - 100 % |
| LOD: | 10 µg/l |
| LLOQ: | 20 µg/l |
| Intraassay precision: | 3.8 % |
| Interassay precision: | 4.0 % |

HPLC Parameters

| | |
|---------------------------|------------------------------------------|
| Pump: | isocratic pump, flow rate: 1.0 ml/min |
| Injection volume: | 50 µl |
| Injection interval: | 10 min |
| Fluorescence detector: | 450 nm (exc.), 530 nm (em.) |
| HPLC-Thermostat: | 40 °C |

Sample Preparation

Extraction:

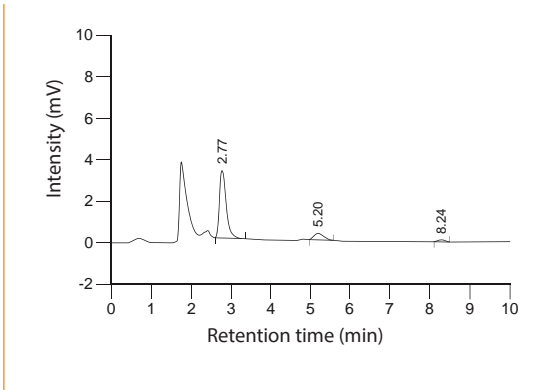
| | |
|-----------------------|-------------------------|
| 200 µl whole blood | 300 µl Precipitant P |
|-----------------------|-------------------------|

1. add 500 µl Stabilising Reagent S
2. centrifuge

HPLC Analysis:

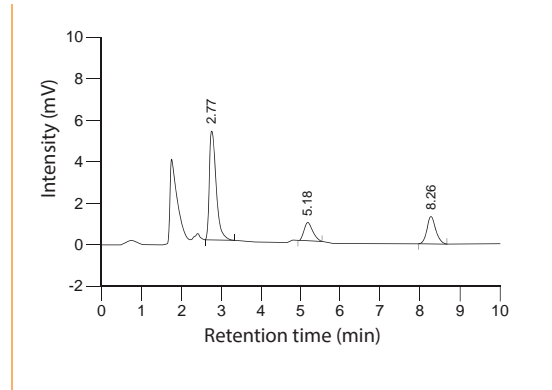
Inject 50 µl of the supernatant

ClinChek® Whole Blood Control, Level I



Flavin adenine dinucleotide: 2.77 min,
 Flavin mononucleotide: 5.20 min,
 Riboflavin: 8.24 min

ClinChek® Whole Blood Control, Level II



Flavin adenine dinucleotide: 2.77 min,
 Flavin mononucleotide: 5.18 min,
 Riboflavin: 8.26 min

Ordering Information

| Order No. | Description | Quantity |
|------------------------------------------|---------------------------------------------------------------------------|---------------|
| 25000 | ClinRep® Complete Kit for Vitamin B2 in Whole Blood for 100 assays | 1 pce. |
| Kit Components (order no. 25000): | | |
| 25010 | Mobile Phase | 1000 ml |
| 25014 | Test Solution, lyophil. | 5 x 2 ml |
| 25015 | Reconstitution Solution R | 10 ml |
| 24513 | Whole Blood Calibrator, lyophil. | 5 x 2 ml |
| 25020 | Sample Preparation Vials | 100 pcs. |
| 25021 | Precipitant P | 30 ml |
| 25022 | Stabilising Reagent S | 50 ml |
| | Manual | 1 pce. |
| | Quick Reference | 1 pce. |
| Start Accessories: | | |
| 27030 | Analytical Column with test chromatogram | 1 pce. |
| 27032 | Guard Column Holder incl. 1 Guard Column | 1 pce. |
| Accessories: | | |
| 27033 | Guard Columns | 5 pcs. |
| FK5810 | PEEK-tubing (connection of prefilter and column) | 1 pce. |
| FK5820 | Stainless steel prefilter holder incl. 1 prefilter | 1 pce. |
| FK5821 | Replacement filter for stainless steel prefilter holder | 10 pcs. |
| ClinChek® Controls: | | |
| 8874 | Whole Blood Control, lyophil., Level I | 10 x 2 ml |
| 8875 | Whole Blood Control, lyophil., Level II | 10 x 2 ml |
| 8876 | Whole Blood Control, lyophil., Level I, II | 2 x 5 x 2 ml |

1.1.6. Vitamin Status

Vitamin B6 in Plasma / Whole Blood

Vitamin B6 consists of three vitamers: pyridoxine, pyridoxal and pyridoxamine. The metabolically active coenzyme form of vitamin B6 is pyridoxal-5'-phosphate (PLP). Clinical signs of vitamin B6 deficiency are mainly expressed in alterations of the skin, neurological disorders, and anemias. In addition to this, a low vitamin B6 status may be responsible for an increase of the homocysteine plasma level (hyperhomocysteinemia). The RECIPE ClinRep® Complete Kit allows the determination of PLP in plasma and whole blood. The test features high analytical sensitivity and can be easily combined with the test kits for the vitamins B1 and B2 (see combi kit).

- Excellent sensitivity: 0.4 µg/l
- Quick sample preparation
- Injection interval: 10 min
- Chromatography combinable with B1 and B2 test kits



Test Data Determination from plasma / from whole blood

| | |
|-----------------------|----------------------------------|
| Linearity: | 0.6 - 800 µg/l / 0.6 - 1500 µg/l |
| Recovery: | 95 - 100 % for both matrices |
| LOD: | 0.4 µg/l for both matrices |
| LLOQ: | 0.6 µg/l for both matrices |
| Intraassay precision: | 2.5 % / 2.3 % |
| Interassay precision: | 3.1 % / 2.9 % |

HPLC Parameters

| | |
|------------------------|------------------------------------------|
| Pump: | isocratic pump, flow rate: 1.0 ml/min |
| Pump (Reagent N): | flow rate: 0.2 ml/min |
| Injection volume: | 50 µl |
| Injection interval: | 10 min |
| Fluorescence detector: | 370 nm (exc.), 470 nm (em.) |
| Temperature: | 25 °C (or ambient) |

Sample Preparation

Extraction:

100 µl sample

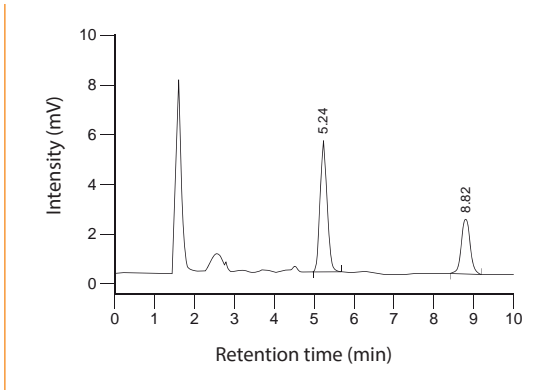
100 µl Precipitant P

centrifuge

HPLC Analysis:

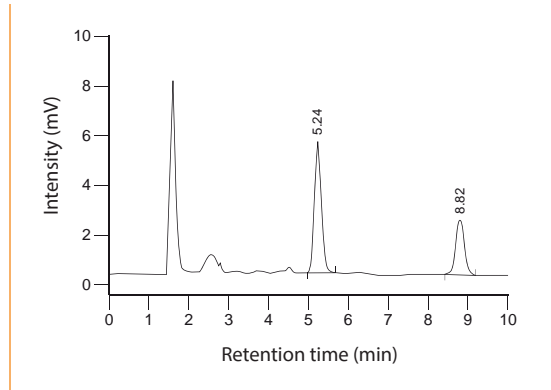
Inject 50 µl of the supernatant

ClinChek® Whole Blood Control, Level I



Pyridoxal-5'-phosphate: 5.24 min, Pyridoxal: 8.82 min

ClinChek® Whole Blood Control, Level II



Pyridoxal-5'-phosphate: 5.24 min, Pyridoxal: 8.82 min

Ordering Information

| Order No. | Description | Quantity |
|------------------------------------------|------------------------------------------------------------------------------------|---------------|
| 26000 | ClinRep® Complete Kit for Vitamin B6 in Plasma / Whole Blood for 100 assays | 1 pce. |
| Kit Components (order no. 26000): | | |
| 26010 | Mobile Phase | 1000 ml |
| 26011 | Standard Solution | 3 ml |
| 26013 | Serum Calibrator, lyophil. | 3 ml |
| 26020 | Sample Preparation Vials | 100 pcs. |
| 26021 | Precipitant P | 10 ml |
| 24626 | Reagent N | 250 ml |
| | Manual | 1 pce. |
| | Quick Reference | 1 pce. |
| Optional Components: | | |
| 24513 | Whole Blood Calibrator, lyophil. | 5 x 2 ml |
| Start Accessories: | | |
| 27030 | Analytical Column with test chromatogram | 1 pce. |
| 27032 | Guard Column Holder incl. 1 Guard Column | 1 pce. |
| Accessories: | | |
| 27033 | Guard Columns | 5 pcs. |
| FK2000 | Peristaltic pump (flow rate 0.2 ml/min) | 1 pce. |
| FK2001 | Replacement tubings for peristaltic pump | 2 pcs. |
| FK5121 | T-Union (PEEK), 1/16" | 1 pce. |
| FK5810 | PEEK-tubing (connection of prefilter and column) | 1 pce. |
| FK5820 | Stainless steel prefilter holder incl. 1 prefilter | 1 pce. |
| FK5821 | Replacement filter for stainless steel prefilter holder | 10 pcs. |
| ClinChek® Controls: | | |
| 8870 | Serum Control, lyophil., Level I | 10 x 5 ml |
| 8871 | Serum Control, lyophil., Level II | 10 x 5 ml |
| 8872 | Serum Control, lyophil., Level III | 10 x 5 ml |
| 8873 | Serum Control, lyophil., Level I, II, III | 3 x 3 x 5 ml |
| 8874 | Whole Blood Control, lyophil., Level I | 10 x 2 ml |
| 8875 | Whole Blood Control, lyophil., Level II | 10 x 2 ml |
| 8876 | Whole Blood Control, lyophil., Level I, II | 2 x 5 x 2 ml |

1.1.6. Vitamin Status

Vitamin B1, B2 in Whole Blood and B6 in Plasma / Whole Blood (CombiKit)

The combi kit enables the combined measurement of the vitamins B1, B2, and B6. It consists of the chromatography kit (order no. 27000) and appropriate sample preparation kits (order nos. 27001, 27002, 27006). The chromatography is performed with a single column for all B-vitamins in subsequent series of measurement. For switching the parameter (e.g. vitamin B1 --> vitamin B2) the parameter settings have to be changed (see HPLC parameters). By selecting the appropriate sample preparation kits, the customer is flexible to choose the parameters according to his needs.

- High flexibility:
1 Chromatography kit
+ 3 sample preparation kits

Test Data

Test data are available on request.

HPLC Parameters Vitamin B1

| | |
|----------------------------|--------------------------------------------|
| Pump (Mobile Phase A + B): | flow rate 1 ml/min ratio A : B = 93 : 7 |
| Pump (Reagent N): | flow rate 0.1 ml/min |
| Injection volume: | 50 µl |
| Injection interval: | 6 min |
| HPLC-Thermostat: | 35 °C |
| Detector (exc. / em.): | 376 nm / 435 nm |
| Retention times: | |
| TPP | approx. 2.5 min |

HPLC Parameters Vitamin B2

| | |
|----------------------------|---------------------------------------------|
| Pump (Mobile Phase A + B): | flow rate 1 ml/min ratio A : B = 80 : 20 |
| Injection volume: | 50 µl |
| Injection interval: | 10 min |
| HPLC-Thermostat: | 40 °C |
| Detector (exc. / em.): | 450 nm / 530 nm |
| Retention times: | |
| FAD | approx. 2.8 min |

HPLC Parameters Vitamin B6

| | |
|----------------------------|---------------------------------------------|
| Pump (Mobile Phase A + B): | flow rate 1 ml/min ratio A : B = 100 : 0 |
| Pump (Reagent N): | flow rate 0.2 ml/min |
| Injection volume: | 50 µl |
| Injection interval: | 10 min |
| HPLC-Thermostat: | 25 °C |
| Detector (exc. / em.): | 370 nm / 470 nm |
| Retention times: | |
| PLP | approx. 5.2 min |



Sample Preparation

Vitamin B1 see page 58, Vitamin B2 see page 60,
Vitamin B6 see page 62

Chromatograms

See chromatograms on page 59 (Vitamin B1),
61 (Vitamin B2), and 63 (Vitamin B6)

Ordering Information

The combi kit consists of the chromatography kit
(order no. 27000) and the separate sample prepara-
tion kits (order nos. 27001, 27002 and 27006).

A: Chromatography

| Order No. | Description | Quantity |
|------------------------------------------|-----------------------------------------------------------------------|-------------------------|
| 27000 | ClinRep® Chromatography Kit for Vitamin B1, B2 and B6 for 1000 assays | 1 pce. |
| Kit Components (order no. 27000): | | |
| 27008 | Mobile Phase A | 4 x 27008 (4 x 2400 ml) |
| 27009 | Mobile Phase B | 2 x 27009 (2 x 1000 ml) |
| 27030 | Analytical Column with test chromatogram | 1 pce. |
| 27033 | Guard Columns | 2 x 27033 (2 x 5 pcs.) |
| FK5821 | Replacement filter for stainless steel prefilter holder | 10 pcs. |
| | Manual | 1 pce. |
| | Quick Reference | 1 pce. |
| Accessories: | | |
| 27032 | Guard Column Holder incl. 1 Guard Column | 1 pce. |
| FK2000 | Peristaltic pump (flow rate 0.2 ml/min) | 1 pce. |
| FK2001 | Replacement tubings for peristaltic pump | 2 pcs. |
| FK5121 | T-Union (PEEK), 1/16" | 1 pce. |
| FK5810 | PEEK-tubing (connection of prefilter and column) | 1 pce. |
| FK5820 | Stainless steel prefilter holder incl. 1 prefilter | 1 pce. |
| ClinChek® Controls: | | |
| 8870 | Serum Control, lyophil., Level I | 10 x 5 ml |
| 8871 | Serum Control, lyophil., Level II | 10 x 5 ml |
| 8872 | Serum Control, lyophil., Level III | 10 x 5 ml |
| 8873 | Serum Control, lyophil., Level I, II, III | 3 x 3 x 5 ml |
| 8874 | Whole Blood Control, lyophil., Level I | 10 x 2 ml |
| 8875 | Whole Blood Control, lyophil., Level II | 10 x 2 ml |
| 8876 | Whole Blood Control, lyophil., Level I, II | 2 x 5 x 2 ml |

B: Sample Preparation

| Order No. | Description | Quantity | |
|------------------------------------------|-----------------------------------------------------------------------------------------|----------|---|
| 27001 | ClinRep® Sample Preparation Kit for Vitamin B1 in Whole Blood for 100 assays | 1 pce. * | |
| Kit Components (order no. 27001): | | | |
| | Identical with order no. 24000 (s. page 59), but without mobile phase | | |
| 27002 | ClinRep® Sample Preparation Kit for Vitamin B2 in Whole Blood for 100 assays | 1 pce. * | |
| Kit Components (order no. 27002): | | | |
| | Identical with order no. 25000 (s. page 61), but without mobile phase | | |
| 27006 | ClinRep® Sample Preparation Kit for Vitamin B6 in Plasma and Whole Blood for 100 assays | 1 pce. * | |
| Kit Components (order no. 27006): | | | |
| | Identical with order no. 26000 (s. page 63), but without mobile phase | | * |

1.1.6. Vitamin Status

25-OH Vitamin D2 / D3 in Plasma and Serum by HPLC

The determination of 25-OH vitamin D2/ D3 is used for the assessment of the vitamin D status. The RECIPE HPLC complete kit enables a quick and reliable quantification of both analytes from plasma and serum. The sample preparation consists of a simple precipitation step, a time-consuming solid phase extraction is not required. The subsequent HPLC analysis is performed with an injection interval of 10 min only. For system check, calibration and internal quality control a ClinTest® Test Solution, a ClinCal® Serum Calibrator (traceable to NIST standard SRM 972a) and ClinChek® Serum Controls are available.

- Quick sample preparation (no solid phase extraction required)
- Injection interval: 10 min
- Traceable to NIST SRM 972a



Test Data

| | |
|-----------------------|--------------------------------------------|
| Linearity: | 3.0 - 500 µg/l (D2) 2.6 - 500 µg/l (D3) |
| Recovery: | 99 - 104 % |
| LOD: | 1.1 µg/l (D2) 1.0 µg/l (D3) |
| LLOQ: | 3.0 µg/l (D2) 2.6 µg/l (D3) |
| Intraassay precision: | 2.7 % (D2) 2.5 % (D3) |
| Interassay precision: | 3.7 % (D2) 3.7 % (D3) |

HPLC Parameters

| | |
|---------------------|------------------------------------------|
| Pump: | isocratic pump, flow rate: 1.0 ml/min |
| Injection volume: | 50 µl |
| Injection interval: | 10 min |
| UV-Detector: | 264 nm |
| HPLC-Thermostat: | 40 °C |

Sample Preparation

Precipitation:

500 µl Precipitant P

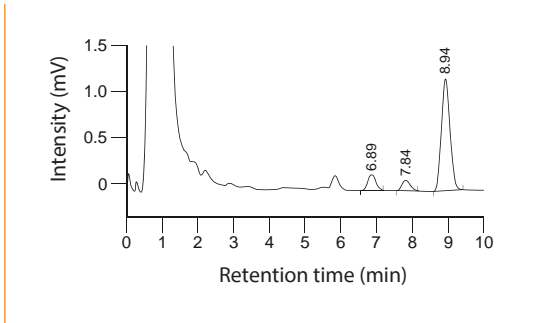
1. Add 400 µl sample
2. Add 400 µl Internal Standard IS

mix, centrifuge

HPLC Analysis:

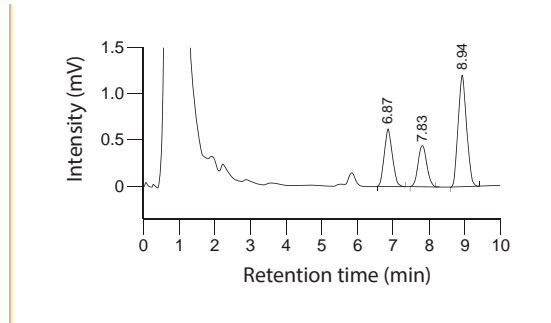
Inject 50 µl of the supernatant

ClinChek® Serum Control, Level I



25-OH Vitamin D3: 6.89 min, 25-OH Vitamin D2: 7.84 min, IS: 8.94 min

ClinChek® Serum Control, Level II



25-OH Vitamin D3: 6.87 min, 25-OH Vitamin D2: 7.83 min, IS: 8.94 min

Ordering Information

| Order No. | Description | Quantity |
|------------------------------------------|-------------------------------------------------------------------------------------------|---------------|
| 35000 | ClinRep® Complete Kit for 25-OH Vitamin D2 / D3 in Plasma and Serum for 100 assays | 1 pce. |
| Kit Components (order no. 35000): | | |
| 35010 | Mobile Phase | 1000 ml |
| 35012 | Internal Standard IS | 50 ml |
| 35013 | Serum Calibrator, lyophil. | 5 x 2 ml |
| 35014 | Test Solution, lyophil. | 2 x 2 ml |
| 35020 | Sample Preparation Vials | 100 pcs. |
| 35021 | Precipitant P | 50 ml |
| | Manual | 1 pce. |
| | Quick Reference | 1 pce. |
| Start Accessories: | | |
| 35030 | Analytical Column with test chromatogram | 1 pce. |
| 35032 | Guard Column Holder incl. 1 Guard Column | 1 pce. |
| Accessories: | | |
| 35033 | Guard Columns | 5 pcs. |
| FK5810 | PEEK tubing (connection of prefilter and column) | 1 pce. |
| FK5820 | Stainless steel prefilter holder incl. 1 prefilter | 1 pce. |
| FK5821 | Replacement filter for stainless steel prefilter holder | 10 pcs. |
| ClinChek® Controls: | | |
| 35080 | Serum Control, lyophil., Level I | 10 x 2 ml |
| 35081 | Serum Control, lyophil., Level II | 10 x 2 ml |
| 35082 | Serum Control, lyophil., Level I, II | 2 x 5 x 2 ml |

1.1.6. Vitamin Status

25-OH Vitamin D2 / D3 in Plasma and Serum by UHPLC

25-OH Vitamins D (D2, D3) are important parameters for the assessment of the vitamin D status. In addition to RECIPE's HPLC complete kit, a ClinRep® Complete Kit for UHPLC systems is available. The UHPLC Complete Kit features a significantly increased sample throughput with reduced buffer consumption due to the very short chromatography duration of only 2 minutes. For system check, calibration and internal quality control a ClinTest® Solution, a ClinCal® Serum Calibrator (traceable to NIST standard SRM 972) and ClinChek® Serum Controls are available.

- UHPLC Kit for Vitamin D
- Injection interval: 2 min
- Traceable to NIST SRM 972



Test Data

| | |
|-----------------------|--------------------------------------------|
| Linearity: | 4.6 - 500 µg/l (D2) 3.7 - 500 µg/l (D3) |
| Recovery: | 99 - 104 % |
| LOD: | 2.8 µg/l (D2) 2.2 µg/l (D3) |
| LLOQ: | 4.6 µg/l (D2) 3.7 µg/l (D3) |
| Intraassay precision: | 4.3 % (D2) 4.6 % (D3) |
| Interassay precision: | 5.9 % (D2) 3.9 % (D3) |

UHPLC Parameters

| | |
|---------------------|-------------------------------------------|
| Pump: | isocratic pump, flow rate: 0.75 ml/min |
| Injection volume: | 5 µl |
| Injection interval: | 2 min |
| UV-Detector: | 264 nm |
| HPLC-Thermostat: | 40 °C |

Sample Preparation

Precipitation:

500 µl Precipitant P

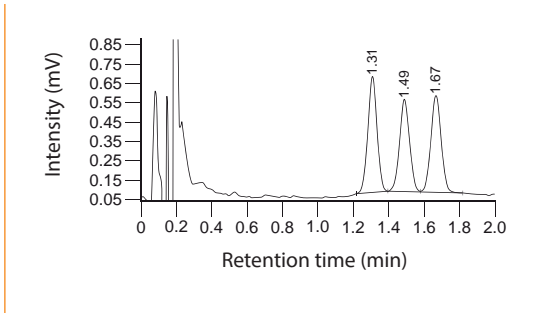
1. Add 400 µl sample
2. Add 400 µl Internal Standard IS

mix, centrifuge

UHPLC Analysis:

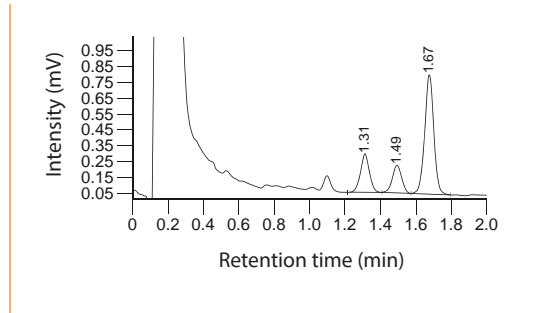
Inject 5 µl of the supernatant

ClinTest® Test Solution



25-OH Vitamin D3: 1.31 min, 25-OH Vitamin D2: 1.49 min,
IS: 1.67 min

ClinCal® Serum Calibrator



25-OH Vitamin D3: 1.31 min, 25-OH Vitamin D2: 1.49 min,
IS: 1.67 min

Ordering Information

| Order No. | Description | Quantity |
|------------------------------------------|-----------------------------------------------------------------------------------------------------|---------------|
| 35100 | ClinRep® Complete Kit for 25-OH Vitamin D2/ D3 in Plasma and Serum with UHPLC for 100 assays | 1 pce. |
| Kit Components (order no. 35100): | | |
| 35110 | Mobile Phase | 1000 ml |
| 35012 | Internal Standard IS | 50 ml |
| 35013 | Serum Calibrator, lyophil. | 5 x 2 ml |
| 35014 | Test Solution, lyophil. | 2 x 2 ml |
| 35020 | Sample Preparation Vials | 100 pcs. |
| 35021 | Precipitant P | 50 ml |
| | Manual | 1 pce. |
| | Quick Reference | 1 pce. |
| Start Accessories: | | |
| 35130 | Analytical Column with test chromatogram | 1 pce. |
| ClinChek® Controls: | | |
| 35080 | Serum Control, lyophil., Level I | 10 x 2 ml |
| 35081 | Serum Control, lyophil., Level II | 10 x 2 ml |
| 35082 | Serum Control, lyophil., Level I, II | 2 x 5 x 2 ml |

1.2.1. Antiarrhythmics

Amiodarone in Plasma

Cardiac arrhythmias are major causes of morbidity and mortality throughout the world. Arrhythmias are controlled by medication of several drugs, such as amiodarone, an antiarrhythmic agent that helps to stabilise the normal rhythm of the heart. The resorption rate and the biological availability of amiodarone is low and extremely variable. The therapy therefore requires a close monitoring for the adjustment of the drug dosage. The RECIPE ClinRep® Complete Kit allows a quick, sensitive and reliable determination of amiodarone and the main metabolite desethylamiodarone. The sample preparation consists of a simple precipitation step.

- Simple and quick sample preparation
- Linearity over a wide range
- Short run time

Test Data

| | |
|-----------------------|---------------------------------------------|
| Linearity: | 0.1 - 10 µg/ml |
| Recovery: | 95 - 105 % |
| LOD: | 0.07 µg/ml |
| LLOQ: | 0.1 µg/ml |
| Intraassay precision: | Amiodarone: 2.1 %, Desethylamiod.: 2.5 % |
| Interassay precision: | Amiodarone: 4.0 %, Desethylamiod.: 4.2 % |

HPLC Parameters

| | |
|---------------------|------------------------------------------|
| Pump: | isocratic pump, flow rate: 0.8 ml/min |
| Injection volume: | 20 µl |
| Injection interval: | 8 min |
| UV/VIS-Detector: | 255 nm |
| HPLC-Thermostat: | 30 °C |

Sample Preparation

Extraction:

100 µl sample

150 µl Precipitant P
(contains Internal Standard IS)

centrifuge

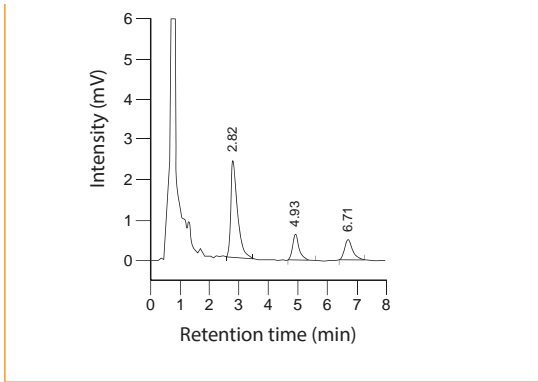
HPLC Analysis:

Inject 20 µl of the supernatant



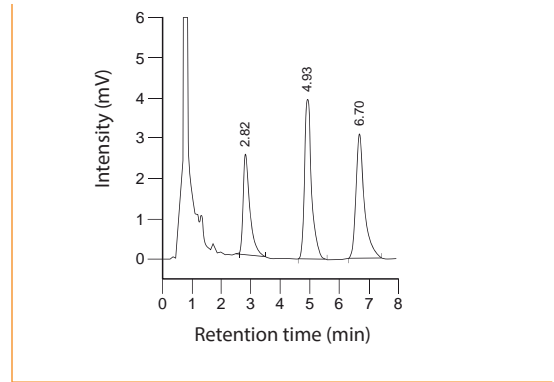
1.2.1. Antiarrhythmics

ClinChek® Serum Control, Level I



IS: 2.82 min, Desethylamiodarone: 4.93 min,
Amiodarone: 6.71 min

ClinChek® Serum Control, Level II



IS: 2.82 min, Desethylamiodarone: 4.93 min,
Amiodarone: 6.70 min

Ordering Information

| Order No. | Description | Quantity |
|------------------------------------------|---------------------------------------------------------------|-------------------------|
| 20000 | ClinRep® Complete Kit for Amiodarone in Plasma for 100 assays | 1 pce. |
| Kit Components (order no. 20000): | | |
| 20010 | Mobile Phase | 1000 ml |
| 20011 | Standard Solution | 3 ml |
| 20012 | Precipitant P with Internal Standard | 15 ml |
| 20013 | Serum Calibrator, lyophil. | 3 ml |
| 20020 | Sample Preparation Vials with Reagent, lyophil. | 2 x 20020 (2 x 50 pcs.) |
| | Manual | 1 pce. |
| | Quick Reference | 1 pce. |
| Start Accessories: | | |
| 20030 | Analytical Column with test chromatogram | 1 pce. |
| 20032 | Guard Column Holder incl. 1 Guard Column | 1 pce. |
| Accessories: | | |
| 20033 | Guard Columns | 5 pcs. |
| FK5810 | PEEK tubing (connection of prefilter and column) | 1 pce. |
| FK5820 | Stainless steel prefilter holder incl. 1 prefilter | 1 pce. |
| FK5821 | Replacement filter for stainless steel prefilter holder | 10 pcs. |
| ClinChek® Controls: | | |
| 20082 | Serum Control, lyophil., Level I, II | 2 x 5 x 3 ml |

Antiasthmatics in Plasma

Theophylline, theobromine and caffeine are termed as methylxanthines and are used in the management of asthma bronchiale. Methylxanthines produce a relaxation of the bronchial smooth muscle and thus are helping to open up constricted airways (bronchodilators). The drug absorption and metabolism may be affected by many factors, including co-medication with other drugs (e.g. several AEDs). A monitoring of the plasma level is therefore essential to ensure that therapeutic, but not toxic drug doses are applied. The RECIPE ClinRep® Complete Kit features simple and quick sample preparation, a cost efficient analysis and ensures reliable results.

- Simultaneous determination of 3 methylxanthines
- Simple and quick sample preparation



Test Data

| | |
|-----------------------|-----------------------------------------------------------------------|
| Linearity: | 1.3 - 50 mg/l |
| Recovery: | approx. 70 % |
| LOD: | Theophylline: 0.8 mg/l Theobromine: 0.6 mg/l Caffeine: 0.6 mg/l |
| LLOQ: | Theophylline: 1.7 mg/l Theobromine: 1.3 mg/l Caffeine: 1.4 mg/l |
| Intraassay precision: | 2.5 % |
| Interassay precision: | 1.7 % |

HPLC Parameters

| | |
|---------------------|------------------------------------------|
| Pump: | isocratic pump, flow rate: 1.5 ml/min |
| Injection volume: | 20 µl |
| Injection interval: | 8 min |
| UV/VIS-Detector: | 273 nm |
| HPLC-Thermostat: | 37 °C |

Sample Preparation

Extraction:

| | |
|---------------|---------------------------------------------------------|
| 100 µl sample | 150 µl Precipitant P (contains Internal Standard IS) |
|---------------|---------------------------------------------------------|

centrifuge



Dilution:

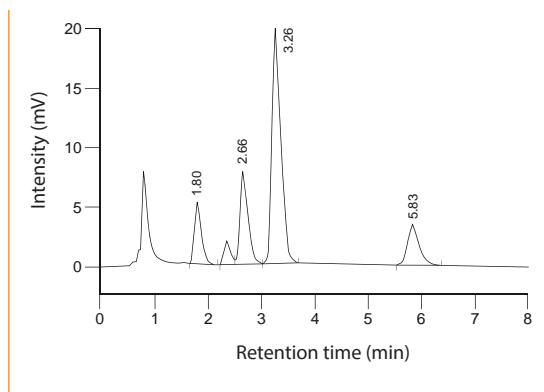
| | |
|-------------------|----------------------------|
| 50 µl supernatant | 250 µl Diluting Solution D |
|-------------------|----------------------------|



HPLC Analysis:

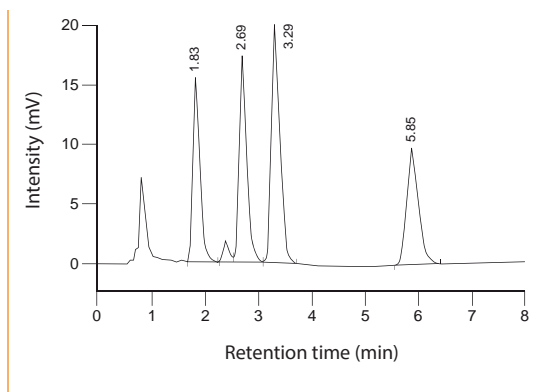
| |
|-----------------------------------------|
| Inject 20 µl of the diluted supernatant |
|-----------------------------------------|

ClinChek® Plasma Control, Level I



Theobromine: 1.80 min, Theophylline: 2.66 min,
IS: 3.26 min, Caffeine: 5.83 min

ClinChek® Plasma Control, Level II



Theobromine: 1.83 min, Theophylline: 2.69 min,
IS: 3.29 min, Caffeine: 5.85 min

Ordering Information

| Order No. | Description | Quantity |
|------------------------------------------|--------------------------------------------------------------------------|-------------------------|
| 12000 | ClinRep® Complete Kit for Antiasthmatics in Plasma for 100 assays | 1 pce. |
| Kit Components (order no. 12000): | | |
| 12010 | Mobile Phase | 1000 ml |
| 12011 | Standard Solution | 4 ml |
| 12012 | Precipitant P with Internal Standard | 15 ml |
| 12013 | Plasma Calibrator, lyophil. | 3 ml |
| 12020 | Sample Preparation Vials with Reagent, lyophil. | 2 x 12020 (2 x 50 pcs.) |
| 12021 | Diluting Solution D | 25 ml |
| | Manual | 1 pce. |
| | Quick Reference | 1 pce. |
| Start Accessories: | | |
| 12030 | Analytical Column with test chromatogram | 1 pce. |
| FK7000 | manu-CART® cartridgeholder, one time accessory | 1 set |
| Accessories: | | |
| FK5810 | PEEK tubing (connection of prefilter and column) | 1 pce. |
| FK5820 | Stainless steel prefilter holder incl. 1 prefilter | 1 pce. |
| FK5821 | Replacement filter for stainless steel prefilter holder | 10 pcs. |
| ClinChek® Controls: | | |
| 12082 | Plasma Control, lyophil., Level I, II | 2 x 5 x 3 ml |

Antiepileptics in Serum

Antiepileptic drugs (AED) are the mainstay of epilepsy treatment. The medication enables the patient to live free of epileptic seizures. Depending on the type of epilepsy, several AEDs with diverse activity mechanisms may be used for the management of the disease. For the monitoring of the drug level, this ClinRep® Complete Kit allows the simultaneous determination of 13* AEDs and metabolites.

* Carbamazepine, carbamazepine-epoxide, N-des-methylmethsuximide, eslicarbazepine, ethosuximide, 10-hydroxycarbamazepine, lamotrigine, oxcarbazepine, phenylethylmalonamide (PEMA), phenobarbital, phenytoin, primidone, sulthiame

- Simultaneous analysis of 13 antiepileptic drugs
- Efficient sample clean-up
- Robust and fast chromatography (injection interval: 15 min)



Test Data

| | |
|-----------------------|-------------------------------------------------------------------------------------|
| Linearity: | Lamotrig., Sulthiame: 0.5 - 50 µg/ml Other Antiepileptics: 0.3 - 300 µg/ml |
| Recovery: | 95 - 105 % |
| LOD: | Lamotrig., Sulthiame: 0.2 µg/ml Other Antiepileptics: 0.1 µg/ml |
| LLOQ: | Lamotrig., Sulthiame: 0.5 µg/ml Other Antiepileptics: 0.3 µg/ml |
| Intraassay precision: | 2.3 % |
| Interassay precision: | 2.8 % |

HPLC Parameters

| | |
|-----------------------|------------------------------------------|
| Pump: | isocratic pump, flow rate: 1.0 ml/min |
| Injection volume: | 10 µl |
| Injection interval: | 15 min |
| UV/VIS-Detector: | |
| Lamotrig., Sulthiame: | 265 nm |
| Other Antiepileptics: | 205 nm |
| HPLC-Thermostat: | 55 °C |

Sample Preparation

Extraction:

| | |
|---------------|---------------------------------------------------------|
| 100 µl sample | 150 µl Precipitant P (contains Internal Standard IS) |
|---------------|---------------------------------------------------------|

centrifuge



Dilution:

| | |
|--------------------|----------------------------|
| 100 µl supernatant | 100 µl Diluting Solution D |
|--------------------|----------------------------|

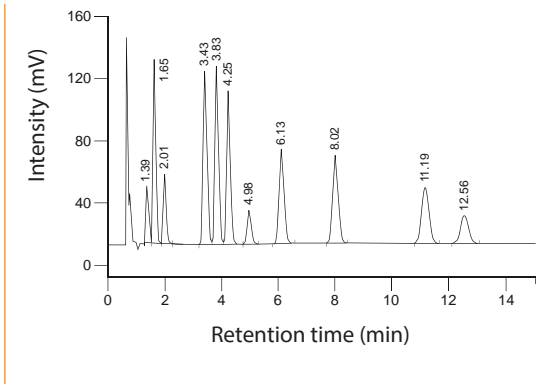


HPLC Analysis:

| |
|-----------------------------------------|
| Inject 10 µl of the diluted supernatant |
|-----------------------------------------|

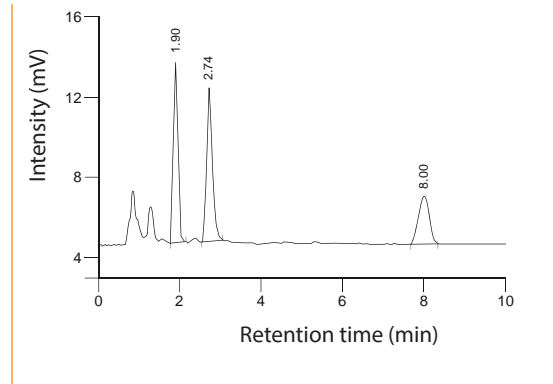
1.2.3. Antiepileptic Drugs

ClinChek® Serum Control, Level II, recorded at 205 nm:



PEMA: 1.39 min, Ethosuximide: 1.65 min, Primidone: 2.01 min, 10-Hydroxy-carbamazepine: 3.43 min, Phenobarbital: 3.83 min, N-Desmethylnmethsuximide: 4.25 min, Carbamazepine-epoxide: 4.98 min, Oxcarbazepine: 6.13 min, IS: 8.02 min, Phenytoin: 11.19 min, Carbamazepine: 12.56 min

ClinChek® Plasma Control, Level II, recorded at 265 nm:



Sulthiame: 1.90 min, Lamotrigine: 2.74 min, IS: 8.00 min

Ordering Information

| Order No. | Description | Quantity |
|------------------------------------------|-------------------------------------------------------------------------|-------------------------|
| 15000 | ClinRep® Complete Kit for Antiepileptics in Serum for 100 assays | 1 pce. |
| Kit Components (order no. 15000): | | |
| 15010 | Mobile Phase | 1000 ml |
| 15011 | Standard Solution Antiepileptics | 3 ml |
| 15012 | Precipitant P with Internal Standard | 15 ml |
| 15013 | Serum Calibrator Antiepileptics, lyophil. | 3 ml |
| 15020 | Sample Preparation Vials with Reagent, lyophil. | 2 x 15020 (2 x 50 pcs.) |
| 15021 | Diluting Solution D | 10 ml |
| | Manual | 1 pce. |
| | Quick Reference | 1 pce. |
| Optional Components: | | |
| 15111 | Standard Solution for Lamotrigine and Sulthiame | 3 ml |
| 15113 | Plasma Calibrator for Lamotrigine and Sulthiame, lyophil. | 3 ml |
| Start Accessories: | | |
| 15030 | Analytical Column with test chromatogram | 1 pce. |
| 15032 | Guard Column Holder incl. 1 Guard Column | 1 pce. |
| Accessories: | | |
| 15033 | Guard Columns | 5 pcs. |
| FK5810 | PEEK tubing (connection of prefilter and column) | 1 pce. |
| FK5820 | Stainless steel prefilter holder incl. 1 prefilter | 1 pce. |
| FK5821 | Replacement filter for stainless steel prefilter holder | 10 pcs. |
| ClinChek® Controls: | | |
| 15082 | Serum Control Antiepileptics, lyophil., Level I, II | 2 x 5 x 3 ml |
| 15182 | Plasma Control for Lamotrigine and Sulthiame, lyophil., Level I, II | 2 x 5 x 3 ml |

Antiepileptics in Serum/ Plasma, *advanced*

In addition to the reliable ClinRep® Complete Kit with order no. 15000, RECIPE offers a new test kit with an advanced chromatography and an extended analyte spectrum. The kit features simultaneous quantification of 16 different antiepileptics and clinically relevant metabolites, including novel drugs such as rufinamide, lacosamide and zonisamide. By use of the same analytical column the kit can easily be combined with the ClinRep® Complete Kit for Levetiracetam.

- Advanced chromatography with 16 AEDs
- Injection interval: 15 min (9 min)
- 1 analytical column for 16 AEDs and Levetiracetam



Test Data

The test data are available on request.

HPLC Parameters

| | |
|---------------------|------------------------------------------|
| Pump: | isocratic pump, flow rate: 1.8 ml/min |
| Injection volume: | 10 µl |
| Injection interval: | 15 min (9 min*) |
| UV-Detector: | 205 nm |
| HPLC-Thermostat: | 30 °C |

* In case samples do not contain carbamazepine and phenytoin, the injection interval can be reduced to 9 min.

Sample Preparation

Extraction:

| | |
|---------------|------------------------------------------------------|
| 100 µl sample | 200 µl Precipitant P (contains Internal Standard) |
|---------------|------------------------------------------------------|

centrifuge



Dilution:

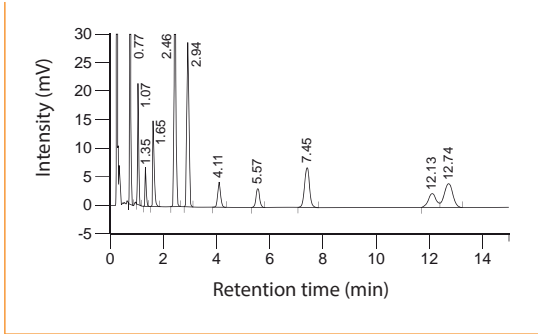
| | |
|--------------------|----------------------------|
| 150 µl supernatant | 250 µl Diluting Solution D |
|--------------------|----------------------------|



HPLC Analysis:

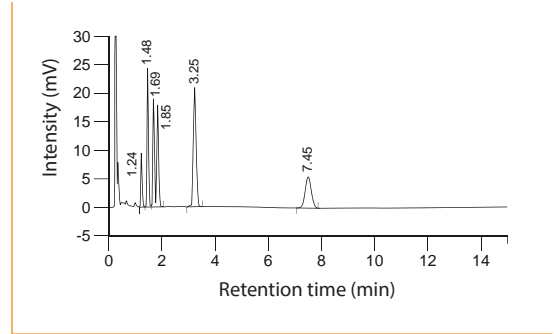
| |
|-----------------------------------------|
| Inject 10 µl of the diluted supernatant |
|-----------------------------------------|

ClinChek® Serum Control, Level II (order no. 14081)



Ethosuximide: 0.77 min, Primidone: 1.07 min,
Sulthiame: 1.35 min, Lamotrigine: 1.65 min,
10-Hydroxy-Carbamazepine: 2.46 min, Phenobarbital: 2.94 min,
Carbamazepine-epoxide: 4.11 min, Oxcarbazepine: 5.57 min,
IS: 7.45 min, Carbamazepine: 12.13 min, Phenytoin: 12.74 min

ClinChek® Serum Control, Level II (order no. 14181)



Lacosamide: 1.24 min, Zonisamide: 1.48 min,
Felbamate: 1.69 min, Rufinamide: 1.85 min,
N-Desmethyilmethsuximide: 3.25 min, IS: 7.45 min

Ordering Information

| Order No. | Description | Quantity |
|------------------------------------------|---------------------------------------------------------------------------------------------|---------------|
| 14000 | ClinRep® Complete Kit, advanced, for Antiepileptics in Serum / Plasma for 100 assays | 1 pce. |
| Kit Components (order no. 14000): | | |
| 14010 | Mobile Phase | 1000 ml |
| 14011 | Standard Solution Antiepileptics 3 | 3 ml |
| 14012 | Precipitant P with Internal Standard | 20 ml |
| 14013 | Serum Calibrator Antiepileptics 3, lyophil. | 3 ml |
| 14020 | Sample Preparation Vials | 100 pcs. |
| 14021 | Diluting Solution D | 25 ml |
| | Manual | 1 pce. |
| | Quick Reference | 1 pce. |
| Optional Components: | | |
| 14111 | Standard Solution Antiepileptics 4 | 3 ml |
| 14113 | Serum Calibrator Antiepileptics 4, lyophil. | 3 ml |
| Start Accessories: | | |
| 14030 | Analytical Column with test chromatogram | 1 pce. |
| Accessories: | | |
| FK5810 | PEEK tubing (connection of prefilter and column) | 1 pce. |
| FK5820 | Stainless steel prefilter holder incl. 1 prefilter | 1 pce. |
| FK5821 | Replacement filter for stainless steel prefilter holder | 10 pcs. |
| ClinChek® Controls: | | |
| 14082 | Serum Control Antiepileptics 3, lyophil., Level I, II | 2 x 5 x 3 ml |
| 14182 | Serum Control Antiepileptics 4, lyophil., Level I, II | 2 x 5 x 3 ml |

Antiepileptics in Serum/ Plasma with UHPLC

This ClinRep® UHPLC Complete Kit shows an identical analyte spectrum as the ClinRep® HPLC Complete Kit with order no. 14000. Thus, the following 16 substances can be quantified simultaneously: carbamazepine, eslicarbazepine, ethosuximide, felbamate, lacosamide, lamotrigine, oxcarbazepine, phenobarbital, phenytoin, primidone, rufinamide, sulthiame and zonisamide as well as the pharmacologically active metabolites N-desmethylnmethsuximide, 10-hydroxycarbamazepine and carbamazepine epoxide. The chromatographic separation is performed with an injection interval of 5 min only.

- Simultaneous determination of 16 AEDs including:
 - Lacosamide
 - Zonisamide
 - Felbamate
 - Rufinamide
 - Eslicarbazepine
- Injection interval: 5 min

Test Data

The test data are available on request.

UHPLC Parameters

| | |
|---------------------|------------------------------------------------|
| Pump: | binary gradient pump, flow rate: 0.4 ml/min |
| Injection volume: | 2 µl |
| Injection interval: | 5 min |
| UV-Detector: | 205 nm |
| HPLC-Thermostat: | 30 °C |

Sample Preparation

Precipitation:

| | |
|---------------|------------------------------------------------------|
| 100 µl sample | 200 µl Precipitant P (contains Internal Standard) |
|---------------|------------------------------------------------------|

centrifuge

Dilution:

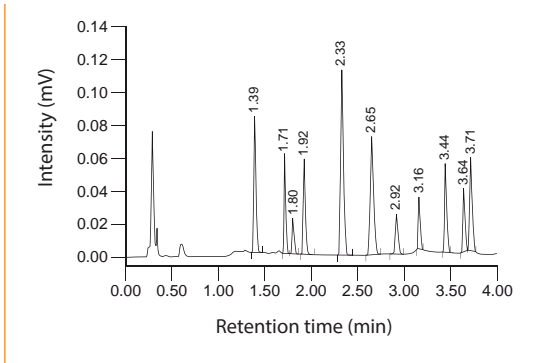
| | |
|--------------------|----------------------------|
| 150 µl supernatant | 250 µl Diluting Solution D |
|--------------------|----------------------------|

UHPLC Analysis:

| |
|----------------------------------------|
| Inject 2 µl of the diluted supernatant |
|----------------------------------------|

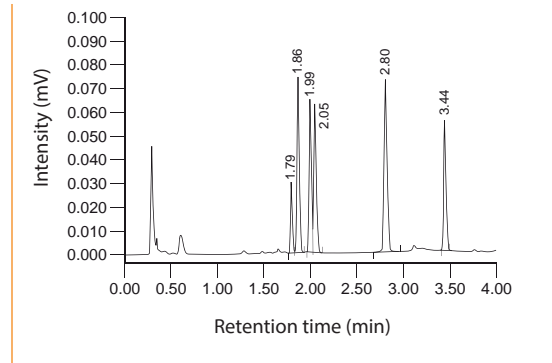


ClinChek® Serum Control, Level II (order no. 14081)



Ethosuximide: 1.39 min, Primidone: 1.71 min,
Sulthiame: 1.80 min, Lamotrigine: 1.92 min, 10-Hydroxy-
Carbamazepine: 2.33 min, Phenobarbital: 2.65 min,
Carbamazepine-epoxide: 2.92 min, Oxcarbazepine: 3.16 min,
IS: 3.44 min, Carbamazepine: 3.64 min, Phenytoin: 3.71 min

ClinChek® Serum Control, Level II (order no. 14181)



Lacosamide: 1.79 min, Zonisamide: 1.86 min,
Felbamate: 1.99 min, Rufinamide: 2.05 min,
N-Desmethylmethsuximide: 2.80 min, IS: 3.44 min

Ordering Information

| Order No. | Description | Quantity |
|------------------------------------------|---------------------------------------------------------------------------|--------------|
| 14100 | ClinRep® Complete Kit for Antiepileptics in Serum / Plasma for 100 assays | 1 pce. |
| Kit Components (order no. 14100): | | |
| 14108 | Mobile Phase A | 400 ml |
| 14109 | Mobile Phase B | 200 ml |
| 14011 | Standard Solution Antiepileptics 3 | 3 ml |
| 14012 | Precipitant P with Internal Standard | 20 ml |
| 14013 | Serum Calibrator Antiepileptics 3, lyophil. | 3 ml |
| 14020 | Sample Preparation Vials | 100 pcs. |
| 14021 | Diluting Solution D | 25 ml |
| | Manual | 1 pce. |
| | Quick Reference | 1 pce. |
| Optional Components: | | |
| 14111 | Standard Solution Antiepileptics 4 | 3 ml |
| 14113 | Serum Calibrator Antiepileptics 4, lyophil. | 3 ml |
| Start Accessories: | | |
| 14130 | Analytical Column with test chromatogram | 1 pce. |
| ClinChek® Controls: | | |
| 14082 | Serum Control Antiepileptics 3, lyophil., Level I, II | 2 x 5 x 3 ml |
| 14182 | Serum Control Antiepileptics 4, lyophil., Level I, II | 2 x 5 x 3 ml |

Lamotrigine and Sulthiame in Plasma

Lamotrigine and sulthiame are important antiepileptic drugs (AED) in the management of several types of epilepsy. This ClinRep® Complete Kit is especially designed for the determination of lamotrigine and sulthiame from plasma. It features a short time for analysis (7 min) and excellent test precision.

- Injection interval: 7 min
- Excellent test precision



Test Data

| | |
|-----------------------|----------------|
| Linearity: | 0.5 - 50 µg/ml |
| Recovery: | 95 - 105 % |
| LOD: | 0.2 µg/ml |
| LLOQ: | 0.5 µg/ml |
| Intraassay precision: | 2.4 % |
| Interassay precision: | 2.6 % |

HPLC Parameters

| | |
|---------------------|------------------------------------------|
| Pump: | isocratic pump, flow rate: 1.0 ml/min |
| Injection volume: | 20 µl |
| Injection interval: | 7 min* |
| UV/VIS-Detector: | 265 nm |
| HPLC-Thermostat: | 55 °C |

* In case the sample contains carbamazepine, the run time must be extended to 15 min.

Sample Preparation

Extraction:

| | |
|---------------|---------------------------------------------------------|
| 100 µl plasma | 150 µl Precipitant P (contains Internal Standard IS) |
|---------------|---------------------------------------------------------|

centrifuge



Dilution:

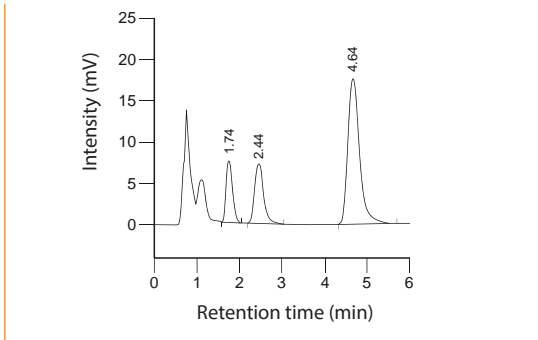
| | |
|--------------------|----------------------------|
| 100 µl supernatant | 100 µl Diluting Solution D |
|--------------------|----------------------------|



HPLC Analysis:

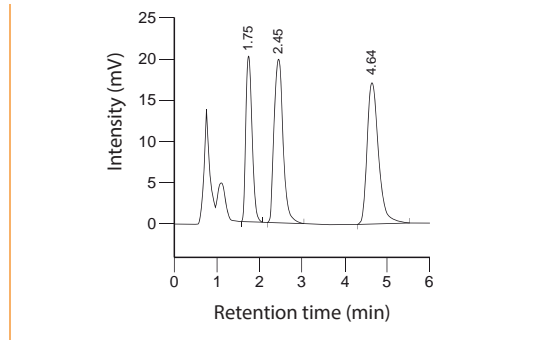
| |
|-----------------------------------------|
| Inject 20 µl of the diluted supernatant |
|-----------------------------------------|

ClinChek® Plasma Control, Level I:



Sulthiame: 1.74 min, Lamotrigine: 2.44 min, IS: 4.64 min

ClinChek® Plasma Control, Level II:



Sulthiame: 1.75 min, Lamotrigine: 2.45 min, IS: 4.64 min

Ordering Information

| Order No. | Description | Quantity |
|------------------------------------------|----------------------------------------------------------------------------------|-------------------------|
| 15100 | ClinRep® Complete Kit for Lamotrigine, Sulthiame in Plasma for 100 assays | 1 pce. |
| Kit Components (order no. 15100): | | |
| 15010 | Mobile Phase | 1000 ml |
| 15111 | Standard Solution | 3 ml |
| 15112 | Precipitant P with Internal Standard | 15 ml |
| 15113 | Plasma Calibrator, lyophil. | 3 ml |
| 15020 | Sample Preparation Vials with Reagent, lyophil. | 2 x 15020 (2 x 50 pcs.) |
| 15021 | Diluting Solution D | 10 ml |
| | Manual | 1 pce. |
| | Quick Reference | 1 pce. |
| Start Accessories: | | |
| 15030 | Analytical Column with test chromatogram | 1 pce. |
| 15032 | Guard Column Holder incl. 1 Guard Column | 1 pce. |
| Accessories: | | |
| 15033 | Guard Columns | 5 pcs. |
| FK5810 | PEEK tubing (connection of prefilter and column) | 1 pce. |
| FK5820 | Stainless steel prefilter holder incl. 1 prefilter | 1 pce. |
| FK5821 | Replacement filter for stainless steel prefilter holder | 10 pcs. |
| ClinChek® Controls: | | |
| 15182 | Plasma Control, lyophil., Level I, II | 2 x 5 x 3 ml |

1.2.3. Antiepileptic Drugs

Levetiracetam (Keppra®) in Serum and Plasma

The RECIPE analytical method for levetiracetam completes the RECIPE kit portfolio for the analysis of antiepileptic drugs (AED) with photometric detection. By the use of the same analytical column, the kits can easily be combined with the AED test kit with order no. 14000 which allows the quantification of further 16 different drugs and clinically relevant metabolites.

- One analytical column for levetiracetam and further 16 AEDs



Test Data

| | |
|-----------------------|------------|
| Linearity: | 0.5 - 1000 |
| Recovery: | 97 - 105 |
| LOD: | 0.15 mg/l |
| LLOQ: | 0.5 mg/l |
| Intraassay precision: | 1.5 |
| Interassay precision: | 1.9 |

HPLC Parameters

| | |
|---------------------|------------------------------------------|
| Pump: | isocratic pump, flow rate: 1.4 ml/min |
| Injection volume: | 20 µl |
| Injection interval: | 6 min |
| UV-Detector: | 205 nm |
| HPLC-Thermostat: | 30 °C |

Sample Preparation

Extraction:

Apply (conditioned* sample preparation column):

| | |
|--------------------|----------------------------------|
| Sample (100 µl) | Internal Standard IS (100 µl) |
|--------------------|----------------------------------|

wash with

1. Washing Solution W1 (3 ml / 1 ml)
2. Washing Solution W2 (1 ml / 330 µl)



Elution:

Apply Eluting Reagent E
(1 ml / 500 µl)



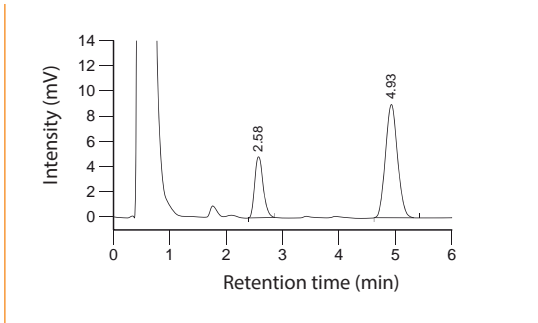
HPLC Analysis:

Inject 20 µl

* Conditioning with Conditioning Reagent C and Washing Solution W1

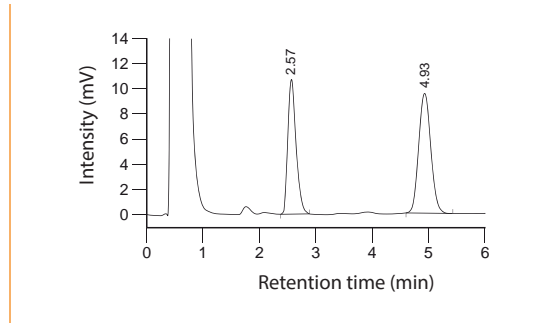
1.2.3. Antiepileptic Drugs

ClinChek® Serum Control, Level I



Levetiracetam: 2.58 min, IS: 4.93 min

ClinChek® Serum Control, Level II



Levetiracetam: 2.57 min, IS: 4.93 min

Ordering Information

| Order No. | Description | Quantity |
|----------------------------|--------------------------------------------------------------------------|-------------------------|
| 15500 | ClinRep® Complete Kit for Levetiracetam in Serum / Plasma for 100 assays | 1 pce. |
| Kit Components : | | |
| 15510 | Mobile Phase | 1000 ml |
| 15520 | Sample Preparation Columns | 2 x 15520 (2 x 50 pcs.) |
| 15522 | Washing Solution W1 | 3 x 15522 (3 x 200 ml) |
| 15511 | Standard Solution | 3 ml |
| 15512 | Internal Standard IS | 10 ml |
| 15513 | Serum Calibrator, lyophil. | 3 ml |
| 15521 | Conditioning Reagent C | 300 ml |
| 15523 | Washing Solution W2 | 100 ml |
| 15524 | Eluting Reagent E | 100 ml |
| | Manual | 1 pce. |
| | Quick Reference | 1 pce. |
| Start Accessories: | | |
| 14030 | Analytical Column with test chromatogram | 1 pce. |
| Accessories: | | |
| FK5810 | PEEK tubing (connection of prefilter and column) | 1 pce. |
| FK5820 | Stainless steel prefilter holder incl. 1 prefilter | 1 pce. |
| FK5821 | Replacement filter for stainless steel prefilter holder | 10 pcs. |
| ClinChek® Controls: | | |
| 15582 | Serum Control, lyophil., Level I, II | 2 x 5 x 3 ml |

1.2.4. Immunosuppressants

Mycophenolic Acid in Plasma

Mycophenolate mofetil (MMF) belongs to the newer immunosuppressive drugs and is usually used in combination with cyclosporine A or tacrolimus. As a pro-drug, MMF is rapidly hydrolysed in vivo to its active constituent mycophenolic acid (MPA). In order to reach an optimal therapeutic efficiency, i.e. to maximise drug efficiency while minimising its toxicity, the administration of MMF requires monitoring of the MPA concentration with subsequent dosage adjustment. For this purpose, our ClinRep® HPLC Complete Kit provides an easy and quick sample preparation and enables a reliable and fast analysis.

- Easy and quick sample preparation
- Reliable chromatography
- Injection interval: 7 min



Test Data

| | |
|-----------------------|---------------|
| Linearity: | 0.1 - 40 mg/l |
| Recovery: | 95 - 105 % |
| LOD: | 0.06 mg/l |
| LLOQ: | 0.1 mg/l |
| Intraassay precision: | 3.3 % |
| Interassay precision: | 4.0 % |

HPLC Parameters

| | |
|---------------------|------------------------------------------|
| Pump: | isocratic pump, flow rate: 1.2 ml/min |
| Injection volume: | 50 µl |
| Injection interval: | 7 min |
| UV/VIS-Detector: | 215 nm |
| HPLC-Thermostat: | 30 °C |

Sample Preparation

Extraction:

| | | |
|------------------|-------------------------------|-------------------------|
| 100 µl plasma | 20 µl Internal Standard IS | 200 µl Precipitant P |
|------------------|-------------------------------|-------------------------|

centrifuge

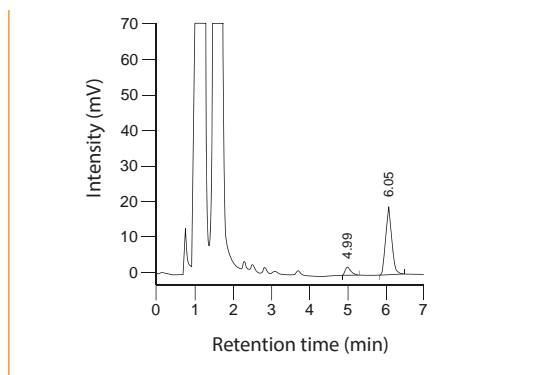


HPLC Analysis:

Inject 50 µl of the supernatant

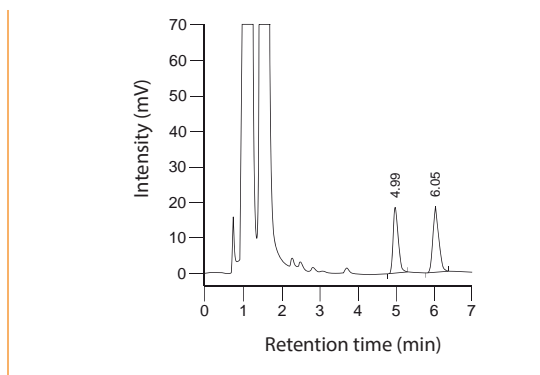
1.2.4. Immunosuppressants

ClinChek® Plasma Control, Level I:



Mycophenolic acid: 4.99 min, IS: 6.05 min

ClinChek® Plasma Control, Level II:



Mycophenolic acid: 4.99 min, IS: 6.05 min

Ordering Information

| Order No. | Description | Quantity |
|------------------------------------------|----------------------------------------------------------------------|--------------|
| 29000 | ClinRep® Complete Kit for Mycophenolic Acid in Plasma for 100 assays | 1 pce. |
| Kit Components (order no. 29000): | | |
| 29010 | Mobile Phase | 1000 ml |
| 29014 | Test Solution | 3 ml |
| 29012 | Internal Standard IS | 2 ml |
| 29013 | Plasma Calibrator, lyophil. | 3 ml |
| 29020 | Sample Preparation Vials | 100 pcs. |
| 29021 | Precipitant P | 20 ml |
| | Manual | 1 pce. |
| | Quick Reference | 1 pce. |
| Start Accessories: | | |
| 29030 | Analytical Column with test chromatogram | 1 pce. |
| Accessories: | | |
| FK5810 | PEEK-tubing (connection of prefilter and column) | 1 pce. |
| FK5820 | Stainless steel prefilter holder incl. 1 prefilter | 1 pce. |
| FK5821 | Replacement filter for stainless steel prefilter holder | 10 pcs. |
| ClinChek® Controls: | | |
| 29083 | Plasma Control, lyophil., Level I, II, III | 3 x 3 x 3 ml |

Atypical Neuroleptics in Plasma / Serum, on-line Analysis

The drugs olanzapine, clozapine, quetiapine, risperidone, and paliperidone (= 9-OH-risperidone) belong to the class of the so called "atypical" neuroleptics and are used for the treatment of schizophrenia. Co-medication, smoking, caffeine and food are factors that extensively influence their metabolism and thus lead to a high intra- and interindividual variability of drug concentrations in blood. In order to avoid severe side effects by overdosing and to ensure an optimal therapeutic effect, therapeutic drug monitoring (TDM) is required. The RECIPE Complete Kit represents a fully automated, robust on-line SPE technique, a direct sample injection into the HPLC system.

- Fully automated method
- On-line sample preparation
- 100 % recovery



Test Data

| | |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------|
| Linearity: | Olz / D-Olz: 5 / 10 - 1000 µg/l Clz / D-Clz: 6 / 5 - 5000 µg/l Qtp: 10 - 2000 µg/l Plp, Rsp: 1 - 200 µg/l |
| Recovery: | 100 % |
| LOD: | 2 µg/l (Olz, Clz, D-Clz), 4 µg/l (D-Olz, Qtp) 0.4 µg/l (Plp, Rsp) |
| LLOQ: | 5 µg/l (Olz), 6 µg/l (Clz), 10 µg/l (D-Olz, Qtp), 4 µg/l (D-Clz) 1 µg/l (Plp, Rsp) |
| Intraassay precision: | 0.2 - 2 % |
| Interassay precision: | 1 - 6 % |

HPLC Parameters

A: Determination of Olz, D-Olz, Clz, D-Clz, Qtp

B: Determination of Plp, Rsp

Isocratic pump 1

(SPE-buffer): flow rates: 0.5 / 1.0 ml/min

Isocratic pump 2

(mobile phase): flow rate: **A:** 1.3 ml/min
B: 1.0 ml/min

Switching valve: 6-port/3-channel
(order no. FK1102)

Injection volume: **A:** 250 µl, **B:** 750 µl

Injection interval: **A:** 22 min, **B:** 20 min

UV-detector: **A:** 254 nm, **B:** 280 nm

HPLC-thermostat: 30 °C

Sample Preparation

Extraction:

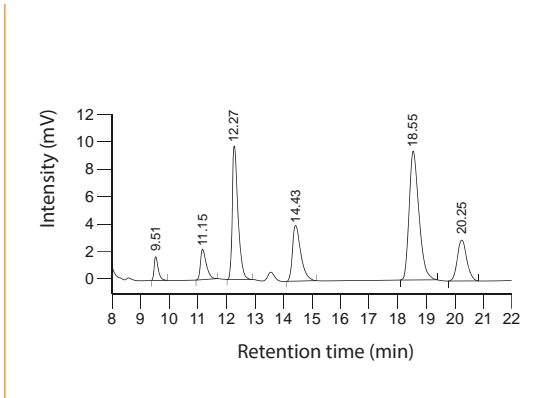
- A:** Add 20 µl Internal Standard IS/ml sample
B: Add 10 µl Internal Standard IS/ml sample

centrifuge

on-line Analysis:

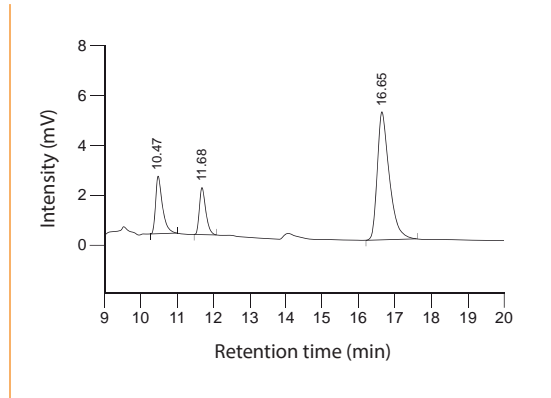
- A:** Inject 250 µl
B: Inject 750 µl

Chromatogram of the plasma calibrator, order no. 40013
(+ 20 µl Internal Standard IS per ml sample, order no. 40012)



Desmethylolanzapine (D-Olz): 9.51 min,
Olanzapine (Olz): 11.15 min, Desmethylclozapine
(D-Clz): 12.27 min, Internal Standard IS: 14.43 min,
Clozapine (Clz): 18.55 min, Quetiapine (Qtp): 20.25 min

Chromatogram of the plasma calibrator, order no. 40113
(+ 10 µl Internal Standard IS per ml sample, order no. 40012)



Paliperidone (Plp): 10.47 min, Risperidone (Rsp): 11.68 min,
Internal Standard IS: 16.65 min

Ordering Information

| Order No. | Description | Quantity |
|------------------------------------------|-----------------------------------------------------------------------------------------|-------------------------|
| 40000 | ClinRep® Complete Kit for Atypical Neuroleptics in Plasma / Serum for 100 assays | 1 pce. |
| Kit Components (order no. 40000): | | |
| 40009 | SPE-Buffer | 2 x 40009 (2 x 1000 ml) |
| 40010 | Mobile Phase | 2 x 40010 (2 x 2000 ml) |
| 40013 | Plasma Calibrator, lyophil. | 5 x 3 ml |
| | Manual | 1 pce. |
| | Quick Reference | 1 pce. |
| Optional Components: | | |
| 40012 | Internal Standard IS | 2 ml |
| 40014 | Test Solution, lyophil. | 5 x 2 ml |
| 40113 | Plasma Calibrator, lyophil., for Risperidone and Paliperidone | 5 x 5 ml |
| 40114 | Test Solution, for Risperidone and Paliperidone | 15 ml |
| Start Accessories: | | |
| 40030 | Analytical Column with test chromatogram | 1 pce. |
| 40031 | SPE-Column | 1 pce. |
| 40032 | Guard Column Holder incl. 1 Guard Column | 1 pce. |
| 40033 | Guard Columns | 5 pcs. |
| FK7400 | Inline-Filter (stainless steel sieve, free of dead volume) | 1 pce. |
| Refill Service: | | |
| 40034 | SPE-Column, refill (original column needs to be returned) | 1 pce. |
| Accessories: | | |
| FK1102 | Switching valve, Sykam (6-port/3-channel) incl. electr. drive, PEEK | 1 pce. |
| FK7340 | Sealings and sieves for order no. FK7400 | 4 pcs. each |
| ClinChek® Controls: | | |
| 40082 | Plasma Control, lyophil., Level I, II | 2 x 5 x 3 ml |
| 40182 | Plasma Control, lyophil., for Risperidone and Paliperidone, Level I, II | 2 x 5 x 5 ml |

ortho-Cresol and Phenol in Urine

o-Cresol is a minor metabolite of toluene and serves for the assessment of an exposure to toluene, which is a frequently used solvent in glues, paints and thinners. In contrast to hippuric acid, which is the main metabolite of toluene, o-cresol is not a physiological component of urine and therefore reflects the internal exposure towards the pollutant. Phenol is the main metabolite of benzene and is used for the assessment of benzene as well as of phenol itself. The RECIPE ClinTox® Complete Kit provides an excellent analytical sensitivity and ensures a reliable biomonitoring of both analytes. The sample clean up is performed via solid phase extraction (SPE).

- Enzymatic release of the analytes
- Sample clean-up via SPE
- Injection interval: 15 min
- High analytical sensitivity



Test Data

| | |
|-----------------------|----------------------------------------------------|
| Linearity: | o-Cresol: 0.05 - 50 mg/l, Phenol: 0.2 - 50 mg/l |
| Recovery: | 85 - 95 % |
| LOD: | o-Cresol: 0.03 mg/l, Phenol: 0.1 mg/l |
| LLOQ: | o-Cresol: 0.05 mg/l, Phenol: 0.2 mg/l |
| Intraassay precision: | o-Cresol: 2.4 %, Phenol: 3.2 % |
| Interassay precision: | o-Cresol: 2.8 %, Phenol: 4.8 % |

HPLC Parameters

| | |
|------------------------|------------------------------------------|
| Pump: | isocratic pump, flow rate: 1.0 ml/min |
| Injection volume: | 10 - 20 µl |
| Injection interval: | 15 min |
| Fluorescence detector: | 277 nm |
| HPLC-Thermostat: | 30 °C |

Sample Preparation

Enzymatic treatment:

| | | | |
|-----------------|---------------------|-------------------------------|--------------------|
| 250 µl urine | 250 µl Reagent C | 50 µl Internal Standard IS | 50 µl Reagent D |
|-----------------|---------------------|-------------------------------|--------------------|

incubate (37 °C, 2 - 24 h)

Extraction:

Transfer the whole sample to a conditioned sample preparation column

wash (2 x 2 ml Reagent B)

Elution:

Elute with 2 ml Reagent A

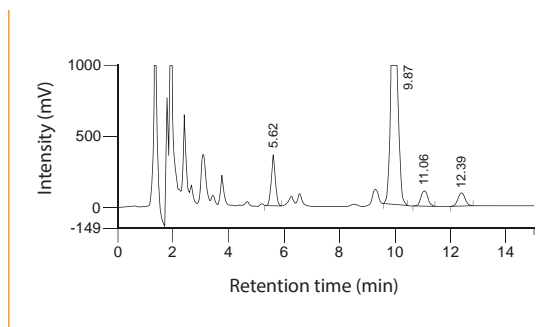
collect the eluate

HPLC Analysis:

Inject 10 - 20 µl

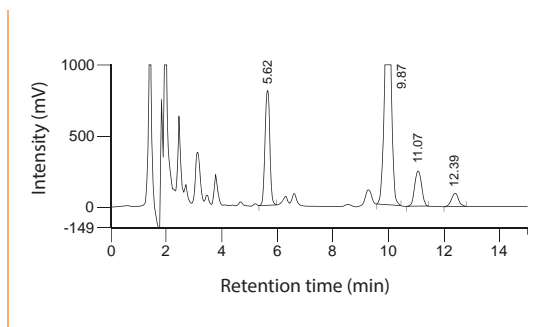
1.3.1. Benzene and Derivatives

ClinChek® Urine Control, Level I:



Phenol: 5.62 min, p-Cresol: 9.87 min, o-Cresol: 11.06 min, IS: 12.39 min

ClinChek® Urine Control, Level II:



Phenol: 5.62 min, p-Cresol: 9.87 min, o-Cresol: 11.07 min, IS: 12.39 min

Ordering Information

| Order No. | Description | Quantity |
|------------------------------------------|------------------------------------------------------------------------------|-------------------------|
| 53000 | ClinTox® Complete Kit for o-Cresol and Phenol in Urine for 100 assays | 1 pce. |
| Kit Components (order no. 53000): | | |
| 53010 | Mobile Phase | 1000 ml |
| 53012 | Internal Standard IS | 5 ml |
| 9925 | Urine Calibrator, lyophil. | 5 x 5 ml |
| 52320 | Sample Preparation Columns | 2 x 52320 (2 x 50 pcs.) |
| 53021 | Reagent A | 400 ml |
| 53022 | Reagent B | 2 x 53022 (2 x 300 ml) |
| 53023 | Reagent C | 25 ml |
| 53024 | Reagent D | 3 x 53024 (3 x 2 ml) |
| | Manual | 1 pce. |
| | Quick Reference | 1 pce. |
| Start Accessories: | | |
| 52330 | Analytical Column with test chromatogram | 1 pce. |
| Accessories: | | |
| FK5810 | PEEK tubing (connection of prefilter and column) | 1 pce. |
| FK5820 | Stainless steel prefilter holder incl. 1 prefilter | 1 pce. |
| FK5821 | Replacement filter for stainless steel prefilter holder | 10 pcs. |
| ClinChek® Controls: | | |
| 8925 | Urine Control, lyophil., Level I, II | 2 x 5 x 5 ml |

Hippuric Acid and Methylhippuric Acids in Urine

This ClinTox® Complete Kit is designed for the reliable biomonitoring of hippuric acid and of o-, m- and p-methylhippuric acid. Those compounds are the urinary metabolites of toluene and of the corresponding xylenes and thus reflect an exposure level towards these pollutants. Sample preparation columns and analytical column of this kit can also be used for the determination of o-cresol and phenol in urine.

- Sample clean-up via SPE
- Injection interval: 8 min
- High analytical sensitivity



Test Data

| | |
|-----------------------|------------------------------------------------------------------------------|
| Linearity: | Hippuric Acid: 50 - 10000 mg/l, Methylhippuric Acids: 5 - 5000 mg/l |
| Recovery: | 85 - 95 % |
| LOD: | Hippuric Acid: 30 mg/l, Methylhip. Acids: 2 mg/l |
| LLOQ: | Hippuric Acid: 50 mg/l, Methylhip. Acids: 4 mg/l |
| Intraassay precision: | Hippuric Acid: 2.0 %, Methylhip. Acids: 2.1 % |
| Interassay precision: | Hippuric Acid: 2.3 %, Methylhip. Acids: 3.2 % |

HPLC Parameters

| | |
|---------------------|------------------------------------------|
| Pump: | isocratic pump, flow rate: 1.0 ml/min |
| Injection volume: | 20 µl |
| Injection interval: | 8 min |
| UV-Detector: | 230 nm |
| HPLC-Thermostat: | 30 °C |

Sample Preparation

Dilution:

| | | |
|-----------------|--------------------------------|-------------------|
| 100 µl urine | 100 µl Internal Standard IS | 2 ml Reagent B |
|-----------------|--------------------------------|-------------------|



Extraction:

Transfer the whole sample to a conditioned sample preparation column

wash (2 x 2 ml Reagent B)



Elution:

Elute with 2 ml Reagent A

collect the eluate

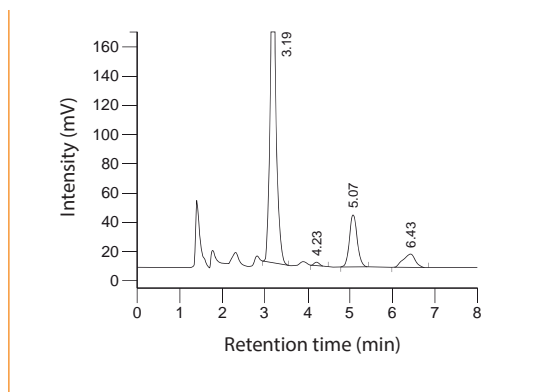


HPLC Analysis:

Inject 20 µl

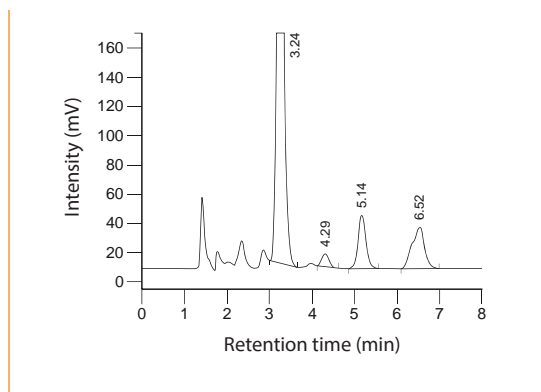
1.3.1. Benzene and Derivatives

ClinChek® Urine Control, Level I:



Hippuric acid: 3.19 min, o-Methylhippuric acid: 4.23 min, IS: 5.07 min, m-/p-Methylhippuric acid: 6.43 min

ClinChek® Urine Control, Level II:



Hippuric acid: 3.24 min, o-Methylhippuric acid: 4.29 min, IS: 5.14 min, m-/p-Methylhippuric acid: 6.52 min

Ordering Information

| Order No. | Description | Quantity |
|------------------------------------------|-------------------------------------------------------------------------------------------------|-------------------------|
| 52000 | ClinTox® Complete Kit for Hippuric Acid and Methylhippuric Acids in Urine for 100 assays | 1 pce. |
| Kit Components (order no. 52000): | | |
| 52010 | Mobile Phase | 1000 ml |
| 52011 | Standard Solution | 3 ml |
| 52012 | Internal Standard IS | 10 ml |
| 9922 | Urine Calibrator, lyophil. | 5 x 5 ml |
| 52320 | Sample Preparation Columns | 2 x 52320 (2 x 50 pcs.) |
| 52021 | Reagent A | 400 ml |
| 52022 | Reagent B | 2 x 52022 (2 x 400 ml) |
| | Manual | 1 pce. |
| | Quick Reference | 1 pce. |
| Start Accessories: | | |
| 52330 | Analytical Column with test chromatogram | 1 pce. |
| Accessories: | | |
| FK5810 | PEEK tubing (connection of prefilter and column) | 1 pce. |
| FK5820 | Stainless steel prefilter holder incl. 1 prefilter | 1 pce. |
| FK5821 | Replacement filter for stainless steel prefilter holder | 10 pcs. |
| ClinChek® Controls: | | |
| 8922 | Urine Control, lyophil., Level I, II | 2 x 5 x 5 ml |

t,t-Muconic Acid in Urine

t,t-Muconic acid is a minor metabolite of benzene and serves for the assessment of an occupational benzene exposure. In contrast to phenol, t,t-muconic acid is not a physiological component of urine and thus provides a higher diagnostic specificity. This ClinTox® Complete Kit represents a robust and sensitive method with a highly selective sample preparation, followed by isocratic separation with UV detection.

- High diagnostic specificity
- Highly selective sample preparation
- High analytical sensitivity

Test Data

| | |
|-----------------------|----------------|
| Linearity: | 0.24 - 20 mg/l |
| Recovery: | 75 - 80 % |
| LOD: | 0.07 mg/l |
| LLOQ: | 0.24 mg/l |
| Intraassay precision: | 5.9 % |
| Interassay precision: | 5.5 % |

HPLC Parameters

| | |
|---------------------|-----------------------------------------|
| Pump: | gradient pump, flow rate: 1.0 ml/min |
| Injection volume: | 50 µl |
| Injection interval: | 18 min |
| UV-Detector: | 264 nm |
| HPLC-Thermostat: | 45 °C |

Sample Preparation

Dilution:

| | | |
|---------------|--------------------------------|-------------------|
| 1 ml urine | 150 µl Internal Standard IS | 1 ml Reagent B |
|---------------|--------------------------------|-------------------|

Extraction:

Transfer the whole sample to a conditioned sample preparation column

wash (2 x 1.5 ml Reagent C)

Elution:

Elute with 2 x 1.5 ml Reagent D

collect the eluate

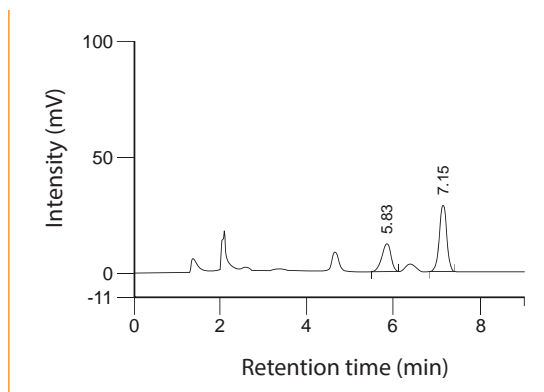
HPLC Analysis:

Inject 50 µl



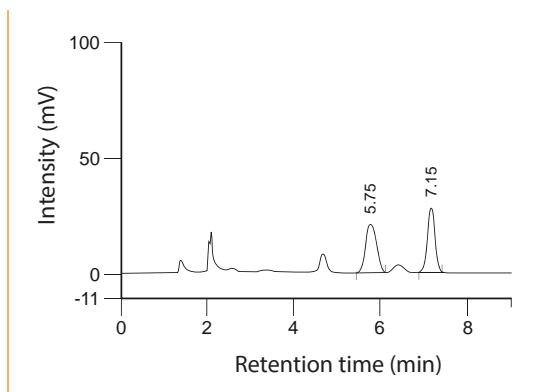
1.3.1. Benzene and Derivatives

ClinChek® Urine Control, Level I:



t,t-Muconic acid: 5.83 min, IS: 7.15 min

ClinChek® Urine Control, Level II:



t,t-Muconic acid: 5.75 min, IS: 7.15 min

Ordering Information

| Order No. | Description | Quantity |
|------------------------------------------|--------------------------------------------------------------------|-------------------------|
| 51000 | ClinTox® Complete Kit for t,t-Muconic Acid in Urine for 100 assays | 1 pce. |
| Kit Components (order no. 51000): | | |
| 51008 | Mobile Phase A | 2 x 51008 (2 x 1000 ml) |
| 51009 | Mobile Phase B | 800 ml |
| 51011 | Standard Solution | 3 ml |
| 51012 | Internal Standard IS | 15 ml |
| 9922 | Urine Calibrator, lyophil. | 5 x 5 ml |
| 51020 | Sample Preparation Columns | 2 x 51020 (2 x 50 pcs.) |
| 51021 | Reagent A | 300 ml |
| 51022 | Reagent B | 400 ml |
| 51023 | Reagent C | 300 ml |
| 51024 | Reagent D | 300 ml |
| | Manual | 1 pce. |
| | Quick Reference | 1 pce. |
| Start Accessories: | | |
| 51030 | Analytical Column with test chromatogram | 1 pce. |
| Accessories: | | |
| FK5810 | PEEK tubing (connection of prefilter and column) | 1 pce. |
| FK5820 | Stainless steel prefilter holder incl. 1 prefilter | 1 pce. |
| FK5821 | Replacement filter for stainless steel prefilter holder | 10 pcs. |
| ClinChek® Controls: | | |
| 8922 | Urine Control, lyophil., Level I, II | 2 x 5 x 5 ml |

1-Hydroxypyrene in Urine, on-line Analysis

Urinary 1-hydroxypyrene is used as a biological index for the assessment of an exposure to polycyclic aromatic hydrocarbons (PAH). Many individual PAHs are genotoxic carcinogens and are formed by the incomplete combustion of fossil fuels. The RECIPE ClinTox® Complete Kit is designed for the automated determination of urinary 1-hydroxypyrene in order to estimate an environmental or occupational related PAH exposure. The sample preparation is performed on-line by column switching using a highly selective SPE-column (SPE: solid phase extraction).

- Fully automated method
- Recovery 100 %
- High analytical sensitivity

Test Data

| | |
|-----------------------|------------------|
| Linearity: | 100 - 24000 ng/l |
| Recovery: | 100 % |
| LOD: | 20 ng/l |
| LLOQ: | 100 ng/l |
| Intraassay precision: | 2.6 % |
| Interassay precision: | 2.9 % |

HPLC Parameters

| | |
|------------------------|-----------------------------------------------|
| Pump 1: | gradient pump, flow rates: 1.0, 1.5 ml/min |
| Pump 2: | isocratic pump: 1.0 ml/min |
| Switching valve: | 6-port/3-channel (order no. FK1103) |
| Injection volume: | 250 µl |
| Injection interval: | 36 min |
| Fluorescence detector: | 242 nm (exc.), 388 nm (em.) |
| HPLC-Thermostat: | 30 °C |

Sample Pretreatment

Enzymatic hydrolysis:

| | | |
|------------|----------------------------|-----------------------|
| 2 ml urine | 1 ml Stabilising Reagent S | 10 µl Enzyme Solution |
|------------|----------------------------|-----------------------|

1. incubate (37 °C, 2 - 36 h)
2. centrifuge

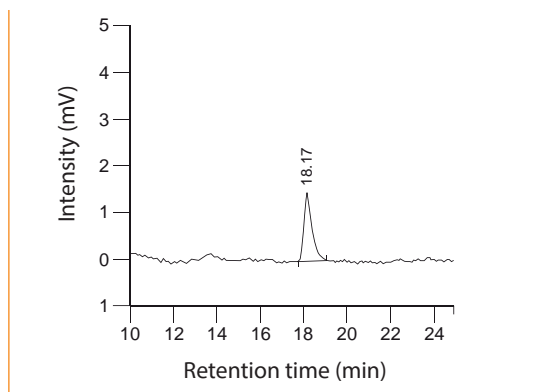
on-line Analysis:

| |
|---------------|
| Inject 250 µl |
|---------------|



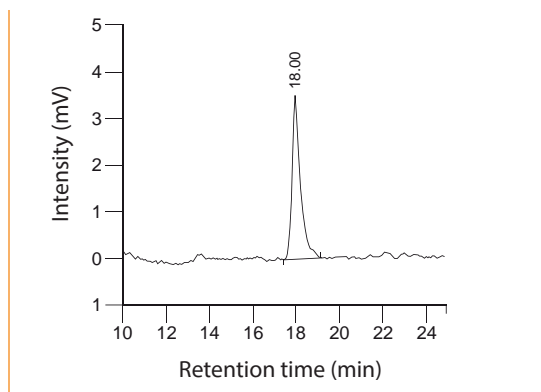
1.3.2. PAH Polycyclic Aromatic Hydrocarbons

ClinChek® Urine Control, Level I:



1-Hydroxypyrene: 18.17 min

ClinChek® Urine Control, Level II:



1-Hydroxypyrene: 18.00 min

Ordering Information

| Order No. | Description | Quantity |
|------------------------------------------|-------------------------------------------------------------------|-------------------------|
| 50000 | ClinTox® Complete Kit for 1-Hydroxypyrene in Urine for 100 assays | 1 pce. |
| Kit Components (order no. 50000): | | |
| 50007 | Mobile Phase A | 1500 ml |
| 50008 | Mobile Phase B | 2 x 50008 (2 x 2000 ml) |
| 50009 | SPE-Buffer | 2 x 50009 (2 x 2500 ml) |
| 9925 | Urine Calibrator, lyophil. | 5 x 5 ml |
| 50021 | Stabilising Reagent S | 200 ml |
| 50022 | Enzyme Solution | 1 ml |
| | Manual | 1 pce. |
| | Quick Reference | 1 pce. |
| Start Accessories: | | |
| 50030 | Analytical Column with test chromatogram | 1 pce. |
| FK7000 | manu-CART® cartridge holder, one time accessory | 1 set |
| 50031 | SPE-Column | 1 pce. |
| 50032 | Guard Columns | 5 pcs. |
| Accessories: | | |
| 50040 | Vials for Sample Pretreatment with Screw Cap, 10 ml | 100 pcs. |
| FK5810 | PEEK-tubing (connection of prefilter and column) | 1 pce. |
| FK5820 | Stainless steel prefilter holder incl. 1 prefilter | 1 pce. |
| FK5821 | Replacement filter for stainless steel prefilter holder | 10 pcs. |
| ClinChek® Controls: | | |
| 8925 | Urine Control, lyophil., Level I, II | 2 x 5 x 5 ml |





2. Photometric Complete Kits

2.1 ClinEasy® Photometry 98

ClinEasy® Complete Kits are designed for the diagnostic screening of urine specimen with photometric detectors.

Our kits are based on test procedures with manual SPE (SPE: solid phase extraction). A complete kit contains all reagents required for sample preparation and subsequent photometric detection. Urine calibrators and controls as well as accessories (e.g. SPE column rack, reagent tubes) are available separately.

5-Aminolevulinic Acid / Porphobilinogen in Urine

This ClinEasy® Complete Kit is designed for the photometric determination of urinary 5-aminolevulinic acid (5-ALA) and porphobilinogen (PBG). Enhanced levels of 5-ALA and PBG are observed with porphyrias and in case of certain intoxications (lead). The sample preparation is performed by combination of special SPE columns for 5-ALA and PBG. In case only PBG shall be determined, a separate ClinEasy® Complete Kit is available. For diagnostic verification a ClinEasy® Complete Kit for the total porphyrins and a ClinRep® HPLC Complete Kit for the differentiated porphyrins are additionally available.

- Easy handling
- Reliable test results



Test Data

| | |
|-----------------------|----------------------------|
| Linearity: | 0.8 - 80 mg/l |
| Recovery: | 72 % (5-ALA) / 87 % (PBG) |
| LOD: | 0.3 mg/l |
| LLOQ: | 0.8 mg/l |
| Intraassay precision: | 5-ALA: 4.6 % PBG: 2.8 % |
| Interassay precision: | 5-ALA: 5.6 % PBG: 5.5 % |

Sample Preparation

Extraction:

Apply 0.5 ml urine to a conditioned
5-ALA / PBG double column

wash (3 x 10 ml HPLC water)

Separate the double column

Colourless column: → **A: Sample Preparation for 5-ALA**
Blue column: → **B: Sample Preparation for PBG**

A: Sample Preparation for 5-ALA

Elution:

Elute with 7.0 ml Reagent A (receiver tube: 500 µl Reagent B)

collect the eluate

Derivatisation:

1. Incubate at 100 °C (water bath, 10 min)
2. Add 7.0 ml Ehrlich's Reagent
3. Incubate at room temperature (15 min)

Analysis:

Photometric measurement

B: Sample Preparation for PBG

Elution:

Elute with 4.0 ml Reagent D

collect the eluate

Derivatisation:

1. Add 4.0 ml Ehrlich's Reagent
2. Incubate at room temperature (15 min)

Analysis:

Photometric measurement

2.1.1 Porphyrria, Lead Intoxication

Ordering Information

| Order No. | Description | Quantity |
|-----------------------------------------|----------------------------------------------------------------------------------------------------|-----------------------|
| 17200 | ClinEasy® Complete Kit for 5-Aminolevulinic Acid and Porphobilinogen in Urine for 50 assays | 1 pce. |
| Kit Components (order no 17200): | | |
| 17220 | Sample Preparation Columns for 5-ALA | 50 pcs. |
| 17320 | Sample Preparation Columns for PBG | 50 pcs. |
| 17221 | Reagent A | 500 ml |
| 17222 | Reagent B | 50 ml |
| 17223 | Reagent C | 2 x 17223 (2 x 7.5 g) |
| 17224 | Reagent D | 200 ml |
| | Manual | 1 pce. |
| | Quick Reference | 1 pce. |
| 17300 | ClinEasy® Complete Kit for Porphobilinogen in Urine for 50 assays | 1 pce. |
| Kit Components (order no 17300): | | |
| 17320 | Sample Preparation Columns for PBG | 50 pcs. |
| 17223 | Reagent C | 7.5 g |
| 17224 | Reagent D | 200 ml |
| | Manual | 1 pce. |
| | Quick Reference | 1 pce. |
| Accessories: | | |
| 17260 | Column Rack (for 20 columns) | 1 pce. |
| FK6300 | Reagent tube (100 x 16 mm) with screw cap and o-ring, PP, autoclavable up to 121 °C | 50 pcs. |
| ClinCal® Calibrator: | | |
| 17213* | Urine Calibrator, lyophil. | 5 x 5 ml |
| 17213m* | Urine Calibrator, lyophil. (available as kit component only) | 1 x 5 ml |
| ClinChek® Controls: | | |
| 17280 | Urine Control, lyophil., Level I | 10 x 5 ml |
| 17281 | Urine Control, lyophil., Level II | 10 x 5 ml |
| 17282 | Urine Control, lyophil., Level I, II | 2 x 5 x 5 ml |

Porphobilinogen in Urine

This ClinEasy® Complete Kit is designed for the photometric determination of urinary porphobilinogen (PBG). Enhanced levels of PBG are observed with porphyrias and in case of certain intoxications (lead). For diagnostic verification additional ClinEasy® Complete Kits for 5-aminolevulinic acid and PBG and the total porphyrins as well as a ClinRep® HPLC Complete Kit for the differentiated porphyrins are available.

- Easy handling
- Reliable test results

Test Data

| | |
|----------------------------|---------------|
| Linearity: | 0.8 - 80 mg/l |
| Recovery: | 87 % |
| LOD: | 0.3 mg/l |
| LLOQ: | 0.8 mg/l |
| Intraassay precision: PGB: | 2.8 % |
| Interassay precision: PGB: | 5.5 % |

Sample Preparation

Extraction:

Apply 0.5 ml urine to a conditioned
PBG column

wash (3 x 10 ml HPLC water)



Elution:

Elute with 4.0 ml Reagent D

collect the eluate



Derivatisation:

1. Add 4.0 ml Ehrlich's Reagent
2. Incubate at ambient temperature (15 min)



Analysis:

Photometric measurement



2.1.1 Porphyria, Lead Intoxication

Ordering Information

| Order No. | Description | Quantity |
|-----------------------------------------|--------------------------------------------------------------------------|---------------|
| 17300 | ClinEasy® Complete Kit for Porphobilinogen in Urine for 50 assays | 1 pce. |
| Kit Components (order no 17300): | | |
| 17320 | Sample Preparation Columns for PBG | 50 pcs. |
| 17223 | Reagent C | 7.5 g |
| 17224 | Reagent D | 200 ml |
| | Manual | 1 pce. |
| | Quick Reference | 1 pce. |
| Accessories: | | |
| FK4000 | Column Rack (for 20 columns) | 1 pce. |
| ClinCal® Calibrator: | | |
| 17213* | Urine Calibrator, lyophil. | 5 x 5 ml |
| 17213m* | Urine Calibrator, lyophil. (available as kit component only) | 1 x 5 ml |
| ClinChek® Controls: | | |
| 17280 | Urine Control, lyophil., Level I | 10 x 5 ml |
| 17281 | Urine Control, lyophil., Level II | 10 x 5 ml |
| 17282 | Urine Control, lyophil., Level I, II | 2 x 5 x 5 ml |

Total Porphyrins in Urine

This ClinEasy® Complete Kit is designed for the photometric determination of the total porphyrins in the diagnosis of porphyrias. In contrast to the HPLC determination of the differentiated porphyrins, the total porphyrin concentration is quantified by a photospectrometer after elution of the urine sample from a sample preparation column. The test is cost-efficient and can be performed quickly and easily. For diagnostic verification additional ClinEasy® Complete Kits for 5-aminolevulinic acid and porphobilinogen as well as for porphobilinogen are available.

- Easy handling
- Reliable test results

Test Data

| | |
|-----------------------|----------------|
| Linearity: | 20 - 4000 µg/l |
| Recovery: | ~ 70 % |
| LOD: | 15 µg/l |
| LLOQ: | 20 µg/l |
| Intraassay precision: | 5.5 % |
| Interassay precision: | 7.2 % |

Sample Preparation

Extraction:

Apply 1.0 ml urine to a conditioned sample preparation column

wash (10 ml HPLC water)



Elution:

Elute with 2.0 ml Eluting Reagent E

collect the eluate



Analysis:

Photometric measurement



2.1.1 Porphyrria, Lead Intoxication

Ordering Information

| Order No. | Description | Quantity |
|------------------------------------------|---------------------------------------------------------------------|---------------|
| 17100 | ClinEasy® Complete Kit for Porphyrins in Urine for 50 assays | 1 pce. |
| Kit Components (order no. 17100): | | |
| 17120 | Sample Preparation Columns | 50 pcs. |
| 17121 | Eluting Reagent E | 200 ml |
| | Manual | 1 pce. |
| | Quick Reference | 1 pce. |
| Accessories: | | |
| FK4000 | Column Rack (for 20 columns) | 1 pce. |
| ClinChek® Controls: | | |
| 17280 | Urine Control, lyophil., Level I | 10 x 5 ml |
| 17281 | Urine Control, lyophil., Level II | 10 x 5 ml |
| 17282 | Urine Control, lyophil., Level I, II | 2 x 5 x 5 ml |





3. LC-MS/MS Complete Kits

- 3.1 ClinMass®
Diagnostics106
- 3.2 ClinMass® TDM
Therapeutic Drug
Monitoring122
- 3.3 ClinSpot® DBS
Dried Blood Spot Analysis152

ClinMass® LC-MS/MS Complete Kits are intended for diagnosis and therapeutic drug monitoring (TDM) in clinical, toxicological and forensic laboratories. ClinSpot® LC-MS/MS Complete Kits are designed for the analysis of dried blood spot (DBS) specimen in newborn screening.

ClinMass® TDM Kit System / ClinMass® TDM Kit System, on-line

Additionally to complete kits, a novel kit system is provided for TDM. It is based on a universal ClinMass® TDM platform that can be used for the analysis of currently 155 different drugs and metabolites. The ClinMass® TDM Kit System is available both for the standard LC-MS/MS configuration as well as for on-line SPE analysis (TDM Kit System, on-line).

Ethylglucuronide and Ethylsulfate in Urine, Plasma and Serum

Ethylglucuronide (EtG) and Ethylsulfate (EtS) are known as relatively new specific parameters for the assessment of alcohol consumption, which dates back several days. The analysis is primarily performed from urine but may be extended to plasma and serum. For this purpose RECIPE offers a ClinMass® Complete Kit for analysis from urine, which can be expanded to plasma and serum samples (ClinMass® Supplement Kit, order no. MS8100). The analytical method features fast and simple sample preparation and guarantees a reliable analyte determination. The kit validation was established in compliance with the German GTFCh guidelines for quality assurance.

- Fast and simple sample preparation
- Method validation according to GTFCh guidelines



Test Data (Urine)

| | |
|-----------------------|---------------------------------------------------|
| Linearity: | EtG: 76.2 - 100000 µg/l EtS: 21.8 - 76356 µg/l |
| LOD: | EtG: 45.7 µg/l / EtS: 13.1 µg/l |
| LLOQ: | EtG: 76.2 µg/l / EtS: 21.8 µg/l |
| Intraassay precision: | EtG: 5.3 % / EtS: 4.6 % |
| Interassay precision: | EtG: 5.4 % / EtS: 4.9 % |

LC-MS/MS Parameters

LC-Parameters

| | |
|---------------------|--------------------------------------------------|
| HPLC pump: | isocratic, flow rates: 0.2 ml/min, 0.5 ml/min |
| Injection volume: | 10 µl |
| Injection interval: | 5 min |
| Column heater: | 40 °C |

MS-Parameters

| | |
|-------------|---------------|
| Ion source: | ESI, negative |
| MS/MS-Mode: | MRM |

Sample Preparation

A: Urine

Dilution / Dotation with IS:

| | |
|-----------------------------------------------|--------------------------------------------------------|
| 50 µl urine (calibrator, control, patient) | 1000 µl Diluting Solution with Internal Standard |
|-----------------------------------------------|--------------------------------------------------------|

LC-MS/MS Analysis:

| |
|--------------|
| Inject 10 µl |
|--------------|

B: Plasma / Serum

Precipitation / Dotation with IS:

| | |
|-------------------------------------------------|---------------------------------------------------|
| 100 µl sample (calibrator, control, patient) | 300 µl Precipitant P with Internal Standard |
|-------------------------------------------------|---------------------------------------------------|

mix, centrifuge

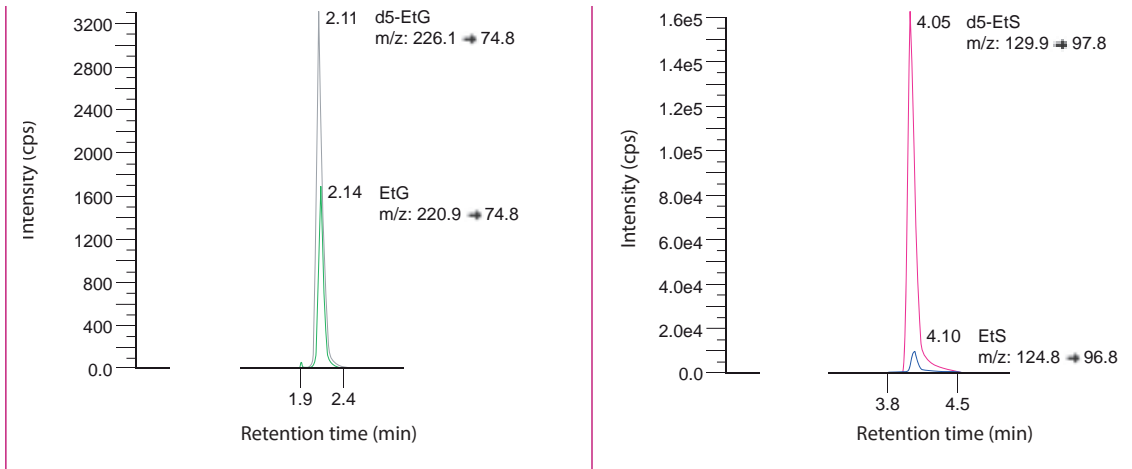
Dilution:

| | |
|----------------------|-------------------------------|
| 50 µl supernatant | 500 µl Diluting Solution D |
|----------------------|-------------------------------|

LC-MS/MS Analysis:

| |
|--------------|
| Inject 10 µl |
|--------------|

Chromatogram of the ClinChek® Urine Control, Level II (order no. MS8081):



Ordering Information

| Order No. | Description | Quantity |
|-------------------------------------------|----------------------------------------------------------------------------------------------------------|-------------------------|
| MS8000 | ClinMass® Complete Kit for Ethylglucuronide and Ethylsulfate in Urine for 400 assays | 1 pce. |
| Kit Components (order no. MS8000): | | |
| MS8005 | Autosampler Washing Solution | 1000 ml |
| MS8010 | Mobile Phase | 1000 ml |
| MS8012 | Diluting Solution with Internal Standard | 4 x MS8012 (4 x 100 ml) |
| MS8713 | Urine Calibrator Set, lyophil., Level 0 - 6 | 7 x 1 x 1 ml |
| | Manual | 1 pce. |
| MS8100 | ClinMass® Supplement Kit for Ethylglucuronide and Ethylsulfate in Plasma and Serum for 100 assays | 1 pce. |
| Kit Components (order no. MS8100): | | |
| MS8112 | Precipitant P with Internal Standard | 30 ml |
| MS8113 | Serum Calibrator Set, lyophil., Level 0 - 3 | 4 x 1 x 1 ml |
| MS8121 | Diluting Solution D | 50 ml |
| Additional Components: | | |
| MS8014 | Optimisation Mix | 2 ml |
| MS8413 | Urine Calibrator Set, lyophil., Level 0 - 3 | 4 x 1 x 1 ml |
| Start Accessories: | | |
| MS8030 | Analytical Column with test chromatogram | 1 pce. |
| ClinChek® Controls: | | |
| MS8080 | Urine Control, lyophil., Level I | 10 x 1 ml |
| MS8081 | Urine Control, lyophil., Level II | 10 x 1 ml |
| MS8082 | Urine Control, lyophil., Level III | 10 x 1 ml |
| MS8083 | Urine Control, lyophil., Level I, II, III | 3 x 3 x 1 ml |
| MS8180 | Serum Control, lyophil., Level I | 10 x 1 ml |
| MS8181 | Serum Control, lyophil., Level II | 10 x 1 ml |
| MS8182 | Serum Control, lyophil., Level I, II | 2 x 5 x 1 ml |

Free Metanephrines in Plasma

► manual sample preparation

Plasma free metanephrines (PFM) are the most specific parameters for the diagnosis of extra-adrenal chromaffin tumors. The measurement of PFMs (metanephrine (M), normetanephrine (NM) and 3-methoxytyramine (MT)) is challenging because of their polar nature, their low molecular weight and their low physiological concentration in human plasma.

This ClinMass® Complete Kit represents a reliable and standardised method for the determination of PFM. In contrast to most of the LC-MS/MS methods established in clinical routine analysis, this method requires no dilution or evaporation steps. Thereby, measurement of highly concentrated samples is guaranteed.

Alternatively to this method with manual sample preparation for standard LC-MS/MS systems, RECIPE offers a LC-MS/MS Complete Kit with on-line SPE analysis

- Highly sensitive and selective LC-MS/MS method
- 5-level calibrator set, controls in 3 levels
- Isotope-labelled internal standard compounds



Test Data

| | |
|-----------------------|-----------------------------------------------------|
| Linearity (up to): | 20970 ng/l (M) 19860 ng/l (NM) 5094 ng/l (MT) |
| Recovery: | 95 - 98 % |
| LOD: | 0.97 ng/l (M), 0.92 ng/l (NM), 0.94 ng/l (MT) |
| LLOQ: | 2.91 ng/l (M), 2.76 ng/l (NM), 2.83 ng/l (MT) |
| Intraassay precision: | 2.0 % (M), 4.4 % (NM), 3.7 % (MT) |
| Interassay precision: | 3.1 % (M), 3.2 % (NM), 3.4 % (MT) |

LC-MS/MS Parameters

LC-Parameters

| | |
|---------------------|------------------------------------|
| Binary HPLC pump: | Mobile Phase A / B (0.6 ml/min) |
| Injection volume: | 20 - 50 µl |
| Injection interval: | 4.0 min |
| Column heater: | 25 °C |

MS-Parameters

| | |
|-------------|--------------|
| Ion-Source: | ESI positive |
| MS/MS-Mode: | MRM |

Sample Preparation

Extraction:

| | |
|-------------------------------------------------|--------------------------------|
| Apply (conditioned* sample preparation column): | |
| 500 µl Sample (calibrator, control, patient) | 500 µl Internal Standard IS |

wash with
Washing Solution W1, W2 and W3

Elution:

| |
|-----------------------------------------|
| Elute with 2 x 100 µl Eluting Reagent E |
|-----------------------------------------|

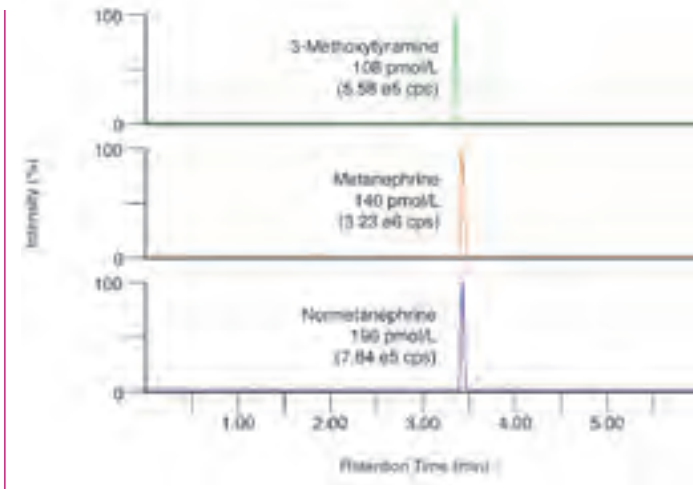
collect the eluate

LC-MS/MS Analysis:

| |
|-------------------|
| Inject 20 - 50 µl |
|-------------------|

* Conditioning with Washing Solution W1 and W2

Chromatogram of the ClinCal[®] Serum Calibrator, level 2 (order no. MS11013)



Ordering Information

| Order No. | Description | Quantity |
|--------------------------------------------|------------------------------------------------------------------------------------------|---------------------------|
| MS11100 | ClinMass[®] Complete Kit for Free Metanephrines in Plasma for 200 assays | 1 pce. |
| Kit Components (order no. MS11100): | | |
| MS11005 | Autosampler Washing Solution | 1000 ml |
| MS11007 | Mobile Phase A | 250 ml |
| MS11008 | Mobile Phase B | 2 x MS11008 (2 x 1000 ml) |
| MS11112 | Internal Standard IS | 2 x MS11112 (2 x 50 ml) |
| MS11013 | Serum Calibrator Set, lyophil. (Level 0 - 4) | 5 x 1 x 3 ml |
| MS11120 | Sample Preparation Columns | 4 x MS11120 (4 x 50 pcs.) |
| MS11121 | Washing Solution W1 | 400 ml |
| MS11122 | Washing Solution W2 | 400 ml |
| MS11123 | Washing Solution W3 | 200 ml |
| MS11124 | Eluting Reagent E | 40 ml |
| | Manual | 1 pce. |
| Additional Components: | | |
| MS11014 | Optimisation Mix | 2 ml |
| Start Accessories: | | |
| MS11030 | Analytical Column with test chromatogram | 1 pce. |
| Accessories: | | |
| MS11161 | Elution Vials | 100 pcs. |
| ClinChek[®] Controls: | | |
| MS11080 | Serum Control, lyophil., Level I | 10 x 3 ml |
| MS11081 | Serum Control, lyophil., Level II | 10 x 3 ml |
| MS11082 | Serum Control, lyophil., Level III | 10 x 3 ml |
| MS11083 | Serum Control, lyophil., Level I, II, III | 3 x 3 x 3 ml |

Free Metanephrines in Plasma

► on-line Analysis

Plasma free metanephrines (PFM) are the most specific parameters for the diagnosis of extra-adrenal chromaffin tumors. The measurement of PFMs (metanephrine (M), normetanephrine (NM) and 3-methoxytyramine (MT)) is challenging because of their polar nature, their low molecular weight and their low physiological concentration in human plasma. Most LC-MS/MS methods used in clinical routine analysis involve time- and labour-consuming manual sample preparation for solid phase extraction (SPE). In contrast to this, the RECIPE ClinMass® Complete Kit represents the first commercially available CE-IVD method and provides a simple sample pretreatment with one-step protein precipitation and subsequent on-line SPE.

- Highly sensitive and selective LC-MS/MS method
- 5-level calibrator set, controls in 3 levels
- Isotope-labelled internal standard compounds

Test Data

| | |
|-----------------------|--------------------------------------------------|
| Linearity (up to): | 5200 ng/l (M), 10000 ng/l (NM, MT) |
| Recovery: | 83 - 116 % |
| LOD: | 1.94 ng/l (M), 3.67 ng/l (NM), 0.94 ng/l (MT) |
| LLOQ: | 5.82 ng/l (M), 11.0 ng/l (NM), 2.83 ng/l (MT) |
| Intraassay precision: | 3.1 % (M), 4.5 % (NM), 3.4 % (MT) |
| Interassay precision: | 3.2 % (M), 4.7 % (NM), 4.1 % (MT) |

LC-MS/MS Parameters

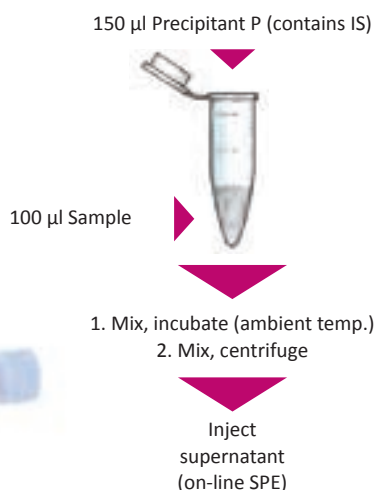
LC-Parameters

| | |
|---------------------|------------------------------------------------|
| Pump 1: | SPE-Buffer (0.1 - 1.0 ml/min) |
| Pump 2: | Mobile Phase A / B (0.6 ml/min) |
| Injection volume: | 50 µl |
| Injection interval: | 6.0 min |
| Switching valve: | automatic switching valve, 6-port/3-channel |
| Column heater: | 25 °C |

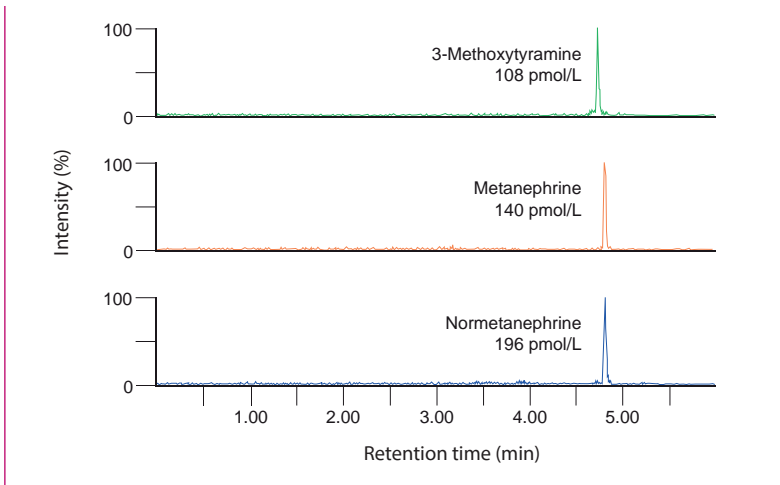
MS-Parameters

| | |
|-------------|---------------|
| Ion-Source: | ESI, positive |
| MS/MS-Mode: | MRM |

Sample Preparation



Chromatogram of the ClinCal® Serum Calibrator, level 2 (order no. MS11013)



Ordering Information

| Order No. | Description | Quantity |
|--------------------------------------------|--------------------------------------------------------------------------------------------------|----------------------------|
| MS11000 | ClinMass® Complete Kit for Free Metanephrines in Plasma – on-line Analysis for 200 assays | 1 pce. |
| Kit Components (order no. MS11000): | | |
| MS11005 | Autosampler Washing Solution | 1000 ml |
| MS11007 | Mobile Phase A | 250 ml |
| MS11008 | Mobile Phase B | 2 x MS11008 (2 x 1000 ml) |
| MS11009 | SPE-Buffer Load L | 2 x MS11009 (2 x 1000 ml) |
| MS11010 | SPE-Buffer Wash W | 1000 ml |
| MS11012 | Precipitant P with Internal Standard | 30 ml |
| MS11013 | Serum Calibrator Set, lyophil. (Level 0 - 4) | 5 x 1 x 3 ml |
| MS11020 | Sample Pretreatment Vials | 2 x MS11020 (2 x 100 pcs.) |
| | Manual | 1 pce. |
| Additional Components: | | |
| MS11014 | Optimisation Mix | 2 ml |
| Start Accessories: | | |
| MS11030 | Analytical Column with test chromatogram | 1 pce. |
| MS11031 | SPE-Column | 1 pce. |
| ClinChek® Controls: | | |
| MS11080 | Serum Control, lyophil., Level I | 10 x 3 ml |
| MS11081 | Serum Control, lyophil., Level II | 10 x 3 ml |
| MS11082 | Serum Control, lyophil., Level III | 10 x 3 ml |
| MS11083 | Serum Control, lyophil., Level I, II, III | 3 x 3 x 3 ml |

Homocysteine in Plasma / Serum

Homocysteine is an established parameter for the risk assessment of degenerative vascular diseases which may lead to heart attack, stroke and thrombosis. The RECIPE ClinMass® Complete Kit allows a reliable determination of total homocysteine for the detection of hyperhomocysteinemia. After an easy sample preparation (reduction and precipitation step) the samples are analysed with an injection interval of 1.0 min only. Optionally, the sample preparation can be performed in 96-well plates.

- Injection interval: 1.0 min



Test Data

| | |
|-----------------------|------------------|
| Linearity: | 0.1 - 106 µmol/l |
| LOD: | 0.01 µmol/l |
| LLOQ: | 0.1 µmol/l |
| Intraassay precision: | 1.9 % |
| Interassay precision: | 4.8 % |

LC-MS/MS Parameters

LC-Parameters

| | |
|---------------------|------------------------|
| Pump: | isocratic (0.7 ml/min) |
| Injection volume: | 1 µl |
| Injection interval: | 1.0 min |
| Column heater: | room temperature |

MS-Parameters

| | |
|-------------|---------------|
| Ion source: | ESI, positive |
| MS/MS-Mode: | MRM |

Sample Preparation

Reduction:

| | |
|------------------------------------------------|-----------------|
| 50 µl sample (+ 50 µl Internal Standard IS) | 50 µl Reagent A |
|------------------------------------------------|-----------------|

mix, incubate
(room temperature, 5 min)

Precipitation:

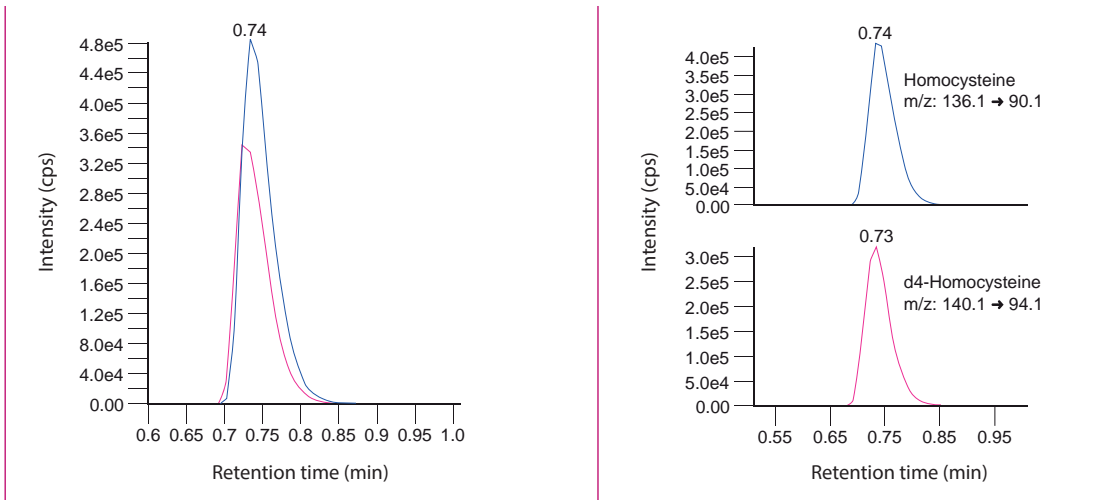
| |
|------------------|
| 200 µl Reagent B |
|------------------|

1. mix, incubate (4 °C, 5 min)
2. centrifuge

LC-MS/MS Analysis:

| |
|--------------------------------|
| Inject 1 µl of the supernatant |
|--------------------------------|

Chromatogram (left) and mass traces (right) of the ClinCal® Serum Calibrator, Level 3 (order no. MS2013)



Ordering Information

| Order No. | Description | Quantity |
|-------------------------------------------|---------------------------------------------------------------------------------|---------------------------|
| MS2000 | ClinMass® Complete Kit for Homocysteine in Plasma / Serum for 300 assays | 1 pce. |
| Kit Components (order no. MS2000): | | |
| MS2005 | Autosampler Washing Solution | 1000 ml |
| MS2010 | Mobile Phase | 800 ml |
| MS2012 | Internal Standard IS, lyophil. | 3 x MS2012 (3 x 5 ml) |
| MS2013 | Serum Calibrator Set, lyophil. (Level 0 - 3) | 4 x 1 x 1 ml |
| MS2020 | Sample Preparation Vials | 3 x MS2020 (3 x 100 pcs.) |
| MS2021 | Reagent A | 3 x MS2021 (3 x 5 ml) |
| MS2022 | Reagent B | 2 x MS2022 (2 x 30 ml) |
| | Manual | 1 pce. |
| Start Accessories: | | |
| MS2030 | Analytical Column with test chromatogram | 1 pce. |
| Accessories: | | |
| FK6501 | Protective Sheets for 96-Well-Plates (PE/PP foil, 80 x 140 mm) | 50 pcs. |
| FK6510 | 96-Well-Plates (370 µl) | 5 pcs. |
| FK6511 | 96-Well-Plates (1200 µl) | 5 pcs. |
| ClinChek® Controls: | | |
| 23082 | Plasma Control, lyophil., Level I, II | 2 x 5 x 3 ml |

Steroids in Serum / Plasma

Steroid hormones are synthesised from cholesterol. The majority of these powerful molecules are produced by the adrenal glands, testes or ovaries. They fulfil a wide range of physiological functions after binding to specific cell receptors of various target organs. They are mainly involved in the carbohydrate, lipid and protein metabolism, stress response and in the regulation of the water and mineral balances, in reproductive processes and the development of secondary sex characteristics. Consequently steroid hormones are also involved in a variety of diseases, like adrenal tumors, the Adrenogenital syndrome (CAH), the Cushing's syndrome or the Polycystic Ovarian Syndrome. The quantitative profiling of steroids is essential in diagnosis and evaluation of pathologic conditions and therapeutic responses.

RECIPE developed a fast and simple quantitative Steroid profiling LC-MS/MS method that covers the most relevant steroid hormones.

- Fast and simple sample preparation
- Injection interval of 6 minutes
- Includes second tier parameters for CAH testing



Test Data

Test data are available on request.

LC-MS/MS Parameters

LC-Parameters

Binary gradient pump: Mobile Phase A / B (0.5 - 0.8 ml/min)
Injection volume: 10 - 40 µl
Injection interval: 6.0 min
Column heater: 40 °C

MS-Parameters

Ion source: Turbo-ionspray (TIS)
ESI, Positive
MS/MS-Mode: MRM

Sample Preparation

Precipitation:

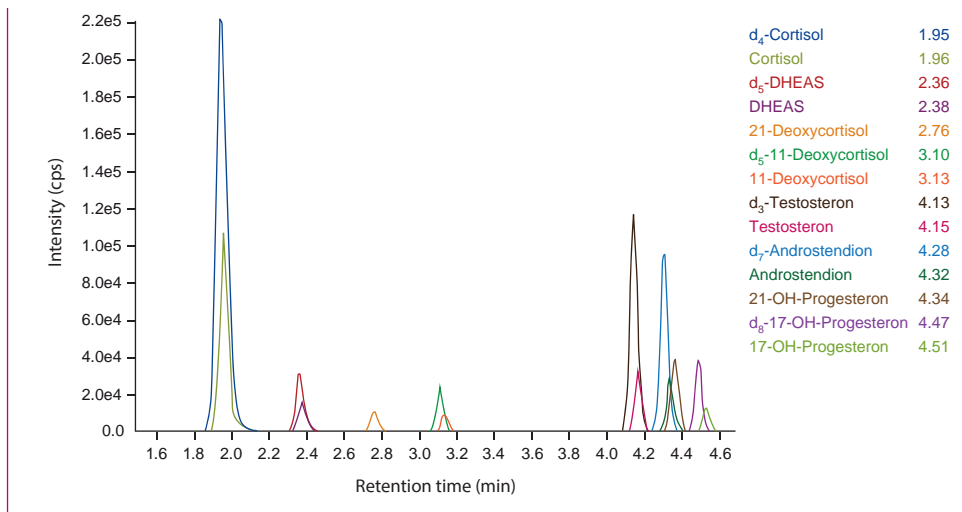
| | |
|------------------------|------------------------------------------------|
| 75 µl Mixture IS/ P | 50 µl sample (calibrator, control, patient) |
|------------------------|------------------------------------------------|

1. mix, precipitate
2. mix, centrifuge

LC-MS/MS Analysis:

| |
|-------------------|
| Inject 10 - 40 µl |
|-------------------|

Chromatogram of the ClinChek® Serum Control, Level II (order no. MS12081):



Ordering Information

| Order No. | Description | Quantity |
|--------------------------------------------|-----------------------------------------------------------------------------|----------------------------|
| MS12000 | ClinMass® Complete Kit for Steroids in Serum / Plasma for 200 assays | 1 pce. |
| Kit Components (order no. MS12000): | | |
| MS12005 | Autosampler Washing Solution | 1000 ml |
| MS12008 | Mobile Phase A | 1000 ml |
| MS12009 | Mobile Phase B | 800 ml |
| MS12012 | Internal Standard IS | 10 ml |
| MS12013 | Serum Calibrator Set, lyophil. (Level 0 - 6) | 7 x 1 x 2 ml |
| MS12020 | Sample Preparation Vials | 2 x MS12020 (2 x 100 pcs.) |
| MS12021 | Precipitant P | 5 ml |
| | Manual | |
| Additional components: | | |
| MS12015 | Optimisation Mix 1 | 2 ml |
| MS12016 | Optimisation Mix 2 | 2 ml |
| Start Accessories: | | |
| MS12030 | Analytical Column with test chromatogram | 1 pce. |
| ClinChek® Controls: | | |
| MS12083 | Serum Control, lyophil., Level I, II, III | 3 x 3 x 2 ml |

Methylmalonic Acid in Serum / Plasma / Urine, *advanced*

Methylmalonic acid (MMA) serves for the assessment of the vitamin B12 status. Vitamin B12 deficiency leads to an increased MMA concentration in serum, plasma and urine. This new RECIPE ClinMass® Complete Kit provides a fast MMA analysis featuring short sample preparation with only one pipetting step (serum, plasma) or direct injection of samples after dilution and addition of IS (urine). The subsequent LC-MS/MS analysis is performed within a 2 min injection interval only while the isobar component succinic acid, which may interfere with MMA, is reliably separated. Calibration and quality control is performed in a convenient and cost-efficient way. The method is fully validated using only one (serum) calibration and control set for all three sample matrices (ClinCal® 4-Level Calibrator Set and ClinChek® Controls).

- One-step sample preparation (serum / plasma)



Test Data

| | |
|-----------------------|----------------------|
| Linearity: | |
| – Serum, Plasma: | 25 - 67745 nmol/l |
| – Urine: | 651 - 1426200 nmol/l |
| LOD: | |
| – Serum, Plasma: | 15 nmol/l |
| – Urine: | 391 nmol/l |
| LLOQ: | |
| – Serum, Plasma: | 25 nmol/l |
| – Urine: | 651 nmol/l |
| Intraassay precision: | 4.3 % |
| Interassay precision: | 5.1 % |

LC-MS/MS Parameters

LC-Parameters

| | |
|-----------------------|------------------------------------|
| Binary gradient pump: | Mobile Phase A / B (0.6 ml/min) |
| Injection volume: | 5 µl |
| Injection interval: | 2.0 min |
| Column heater: | 40 °C |

MS-Parameters

| | |
|-------------|---------------------------------------|
| Ion source: | Turbo-ionspray (TIS) ESI, negative |
| MS/MS-Mode: | MRM |

Sample Preparation

Precipitation / Addition of IS:

| | |
|------------------------------------------------------|--------------------------------------------------|
| 400 µl P Precipitant (contains internal standard) | 100 µl sample* (calibrator, control, patient) |
|------------------------------------------------------|--------------------------------------------------|

mix and centrifuge

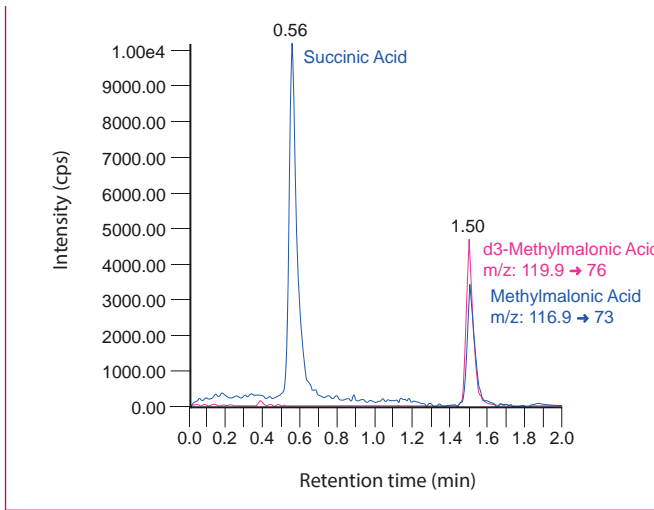


LC-MS/MS Analysis:

Inject 5 µl of the sample

* Urines are diluted (50 µl urine + 1000 µl Diluting Solution D)

Chromatogram of the ClinChek® Serum Control, Level I (order no. MS5080)



Ordering Information

| Order No. | Description | Quantity |
|-------------------------------------------|-----------------------------------------------------------------------------------------------------------|---------------------------|
| MS5100 | ClinMass® Complete Kit, <i>advanced</i> , for Methylmalonic Acid in Serum / Plasma / Urine for 300 assays | 1 pce. |
| Kit Components (order no. MS5100): | | |
| MS5005 | Autosampler Washing Solution | 1000 ml |
| MS5108 | Mobile Phase A | 1000 ml |
| MS5109 | Mobile Phase B | 330 ml |
| MS5112 | Precipitant P with Internal Standard | 3 x MS5112 (3 x 40 ml) |
| MS5013 | Serum Calibrator Set, lyophil., (Level 0 - 3) | 4 x 1 x 2 ml |
| MS5020 | Sample Preparation Vials | 3 x MS5020 (3 x 100 pcs.) |
| | Manual | 1 pce. |
| Additional Components: | | |
| MS5114 | Optimisation Mix | 2 ml |
| MS5021 | Diluting Solution D for Urine | 50 ml |
| Start Accessories: | | |
| MS5130 | Analytical Column with test chromatogram | 1 pce. |
| ClinChek® Controls: | | |
| MS5082 | Serum Control, lyophil., Level I, II | 2 x 5 x 2 ml |

3.1.4 Vitamin Status

Vitamins B1, B2, B6 in Whole Blood

This new kit enables the combined measurement of the vitamins B1, B2 and B6 in one run. The vitamins that are analysed are thiamine pyrophosphate TPP (vitamin B1; synonym: thiamine diphosphate TDP), flavin adenine dinucleotide FAD (vitamin B2), pyridoxal PL and pyridoxal 5'-phosphate PLP (both vitamin B6). The determination of B-vitamins (B1, B2 and B6) is performed in case of suspected neuropathy. Deficiencies can also occur in case of diabetes type 1 and 2. It is also reasonable to determine B-vitamins when searching for the cause of lack of concentration with suspected nutritional deficiency.

- Injection interval:
4.0 min (Vitamins B1, B2, B6)
2.5 min (Vitamins B1, B6)
- One-step sample preparation

Test Data

| | |
|-----------------------|-------------------------------------------------------------------------------------------------|
| Linearity: | 5.74 – 300 µg/l (TPP) 8.11 – 1200 µg/l (FAD) 0.81 – 80 µg/l (PL) 4.56 – 200 µg/l (PLP) |
| LOD: | 1.87 µg/l (TPP), 2.68 µg/l (FAD) 0.25 µg/l (PL), 1.72 µg/l (PLP) |
| LLMI: | 5.74 µg/l (TPP), 8.11 µg/l (FAD) 0.81 µg/l (PL), 4.56 µg/l (PLP) |
| Intraassay precision: | 7.9 % (TPP), 5.8 % (FAD) 2.0 % (PL), 8.1 % (PLP) |
| Interassay precision: | 6.9 % (TPP), 6.7 % (FAD) 6.8 % (PL), 14.0 % (PLP) |

LC-MS/MS Parameters

| LC-Parameters | Vitamins B1, B2, B6 |
|-----------------------|---------------------------------------------|
| Binary gradient pump: | Mobile Phases A / B (0.30 – 0.45 ml/min) |
| Injection volume: | 5 – 50 µl |
| Injection interval: | 4.0 min |
| Column heater: | 25 °C |
| LC-Parameters | Vitamins B1, B6 |
| Binary gradient pump: | Mobile Phases A / B (0.30 – 0.60 ml/min) |
| Injection volume: | 5 – 50 µl |
| Injection interval: | 2.5 min |
| Column heater: | 25 °C |
| MS-Parameters | |
| Ion source: | ESI, positive |
| MS/MS-Mode: | MRM |

Sample Preparation

Measurement of Vitamins B1, B2, B6

Precipitation / Addition of IS:

| | | |
|-------------------------|---------------------------------------------------|-------------------------------------|
| 100 µl Precipitant P | 50 µl sample (calibrator, control, patient) | 20 µl Internal Standard in water |
|-------------------------|---------------------------------------------------|-------------------------------------|

mix and centrifuge



LC-MS/MS Analysis:

Inject 5 – 50 µl of the supernatant



Measurement of Vitamins B1, B6

Precipitation / Addition of IS:

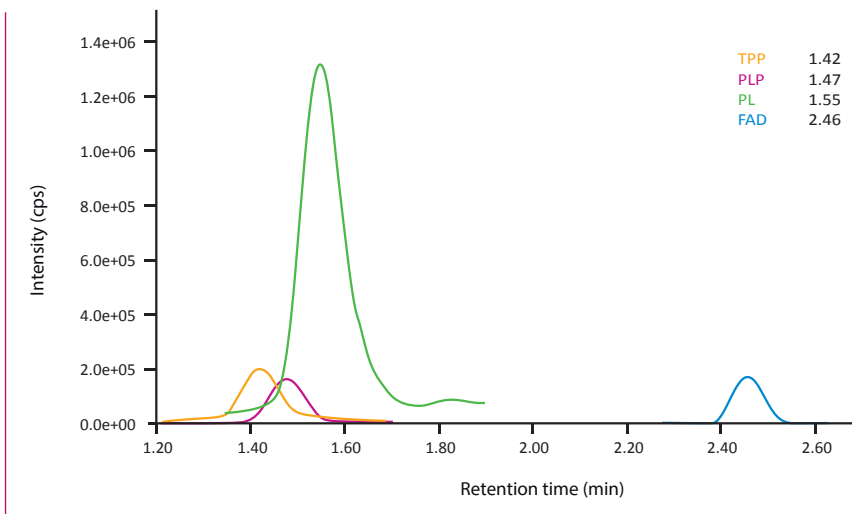
| | |
|----------------------------------------------|------------------------------------------------|
| 100 µl Internal Standard in Precipitant P | 50 µl sample (calibrator, control, patient) |
|----------------------------------------------|------------------------------------------------|

mix and centrifuge

LC-MS/MS Analysis:

Inject 5 – 50 µl of the supernatant

Chromatogram of the ClinChek® Whole Blood Control, Level II (order no. MS13081)



Ordering Information

| Order No. | Description | Quantity |
|--------------------------------------------|-------------------------------------------------------------------------------------|---------------|
| MS13000 | ClinMass® Complete Kit for Vitamins B1, B2, B6 in Whole Blood for 400 assays | 1 pce. |
| Kit Components (order no. MS13000): | | |
| MS13005 | Autosampler Washing Solution | 1000 ml |
| MS13008 | Mobile Phase A | 1000 ml |
| MS13009 | Mobile Phase B | 300 ml |
| MS13012 | Internal Standard IS, lyophil. | 3 vials |
| MS13013 | Whole Blood Calibrator Set, lyophil. (Level 0 – 3) | 4 x 1 x 1 ml |
| MS13020 | Sample Preparation Vials | 100 pcs. |
| MS13021 | Precipitant P | 25 ml |
| | Manual | 1 pce. |
| Additional Components: | | |
| MS13014 | Optimisation Mix, lyophil. | 2 ml |
| Start Accessories: | | |
| MS13030 | Analytical Column with test chromatogram | 1 pce. |
| ClinChek® Controls: | | |
| MS13082 | Whole Blood Control, lyophil., Level I, II | 2 x 5 x 1 ml |

3.1.4 Vitamin Status

25-OH Vitamin D2 / D3 in Plasma and Serum

► on-line Analysis

The ClinMass® Complete Kit with order nos. MS7000 enables a fast on-line SPE LC-MS/MS analysis of 25-OH-Vitamin D (D2, D3) with an injection interval of 3 min only. The C-3 epimer of 25-OH vitamin D3 (3-epi-25-OH vitamin D3) is separated reliably from the analyte peak. An analytical column with a run time of 4 min (order no. MS7035) is additionally available in order to obtain baseline separation.

- Fast on-line analysis (injection interval: 3 min)
- Separation of the C-3 epimer
- Traceable to NIST SRM 972

Test Data

| | |
|-----------------------|--------------------------------------------|
| Linearity: | 1.4 - 250 µg/l (D2) 2.3 - 250 µg/l (D3) |
| LOD: | 0.4 µg/l (D2) 0.7 µg/l (D3) |
| LLOQ: | 1.4 µg/l (D2) 2.3 µg/l (D3) |
| Intraassay precision: | 6.8/3.9 % (D2) 4.7/3.3 % (D3) |
| Interassay precision: | 7.6/4.3 % (D2) 6.6/4.2 % (D3) |

LC-MS/MS Parameters

LC-Parameters

| | |
|---------------------|----------------------------------------|
| Pump 1: | SPE-Buffer (0.1 - 5.0 ml/min) |
| Pump 2: | Mobile Phase (0.5 ml/min) |
| Injection volume: | 10 - 50 µl |
| Injection interval: | 3 min (4 min) |
| Switching valve: | 6-port/3-channel (order no. FK1102) |
| Column heater: | 40 °C |

MS-Parameters

| | |
|-------------|--------------------------------------|
| Ion source: | Heated Nebulizer (APCl), positive |
| MS/MS-Mode: | MRM |

Sample Pretreatment

Precipitation:

| | |
|------------------------|------------------------------------------------|
| 150 µl mixture IS/P | 50 µl sample (calibrator, control, patient) |
|------------------------|------------------------------------------------|

1. mix, incubate (4 °C)
2. mix, centrifuge

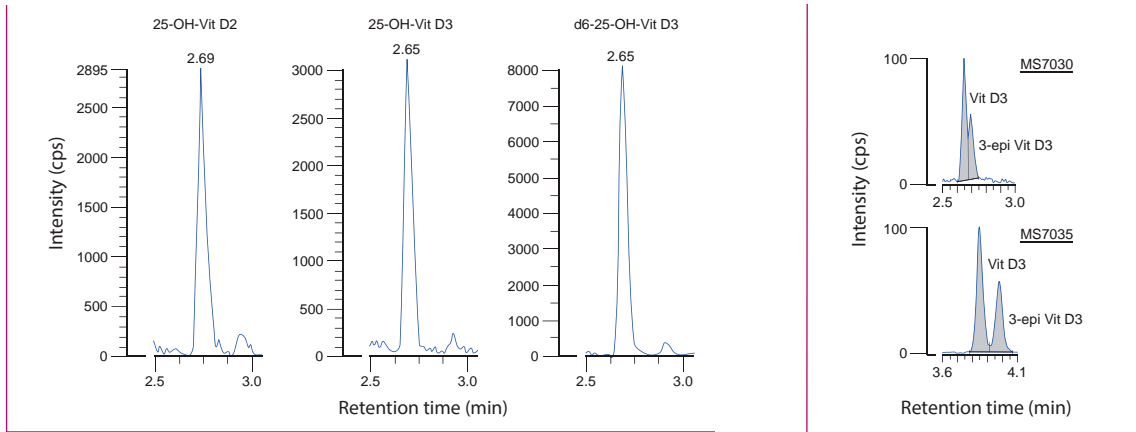
on-line Analysis:

| |
|-------------------|
| Inject 10 - 50 µl |
|-------------------|



left: ClinCal® Serum Calibrator, order no. MS7013, level 2 (25-OH vitamin D2 and D3) and ClinMass® Internal Standard, order no. MS7012 (d6-25-OH vitamin D3)

right: Human serum with 25-OH vitamin D3 and 3-epi-25-OH vitamin D3, measured with the 3-min method (top) and 4-min method (bottom)



Ordering Information

| Order No. | Description | Quantity |
|-------------------------------------------|--------------------------------------------------------------------------------------------------------|---------------------------|
| MS7000 | ClinMass® Complete Kit for 25-OH Vitamin D2 / D3 in Plasma and Serum for 300 assays | 1 pce. |
| Kit Components (order no. MS7000): | | |
| MS7005 | Autosampler Washing Solution | 1000 ml |
| MS7009 | SPE-Buffer | 2 x MS7009 (2 x 1000 ml) |
| MS7010 | Mobile Phase | 700 ml |
| MS7012 | Internal Standard IS | 30 ml |
| MS7013 | Serum Calibrator Set, lyophil. (Level 0 - 3) | 4 x 1 x 1 ml |
| MS7020 | Sample Pretreatment Vials | 3 x MS7020 (3 x 100 pcs.) |
| MS7021 | Precipitant P | 15 ml |
| | Manual | 1 pce. |
| Additional Components: | | |
| MS7014 | Optimisation Mix | 2 ml |
| MS7015 | Optimisation Mix 3-epi | 1 ml |
| Start Accessories: | | |
| MS7030 | Analytical Column with test chromatogram | 1 pce. |
| MS7035 | Analytical Column 3-epi with test chromatogram (for the additional analysis of 3-epi-25-OH Vitamin D3) | 1 pce. |
| MS7031 | SPE-Column | 1 pce. |
| Accessories: | | |
| FK7400 | Inline-Filter (stainless steel sieve, free of dead volume) | 1 pce. |
| ClinChek® Controls: | | |
| MS7080 | Serum Control, lyophil., Level I | 10 x 1 ml |
| MS7081 | Serum Control, lyophil., Level II | 10 x 1 ml |
| MS7082 | Serum Control, lyophil., Level I, II | 2 x 5 x 1 ml |

3.1.4 Vitamin Status

25-OH Vitamin D2 / D3 in Plasma and Serum

- ▶ automated on-line Analysis
- ▶ automated on-line Analysis with Filter-Plates

The ClinMass® Complete Kits with order nos. MS7100 and MS7200 enable fast on-line SPE LC-MS/MS analysis of 25-OH-Vitamin D (D2, D3) with an injection interval of 3 min only. In order to meet laboratory demands in high sample throughput for Vitamin D RECIPE has developed a fully automated sample preparation kit for many liquid handling devices with the option to use 96-well filter plates as well. The C-3 epimer of 25-OH vitamin D3 (3-epi-25-OH vitamin D3) is separated reliably from the analyte peak. An analytical column with a run time of 4 min (order no. MS7035) is additionally available in order to obtain baseline separation.

- Automated sample preparation
- Fast on-line analysis (injection interval: 3 min)
- Separation of the C-3 epimer
- Traceable to NIST SRM 972.



Test Data

| | |
|-----------------------|--------------------------------------------|
| Linearity: | 1.4 - 250 µg/l (D2) 2.3 - 250 µg/l (D3) |
| LOD: | 0.4 µg/l (D2) 0.7 µg/l (D3) |
| LLOQ: | 1.4 µg/l (D2) 2.3 µg/l (D3) |
| Intraassay precision: | 6.8/3.9 % (D2) 4.7/3.3 % (D3) |
| Interassay precision: | 7.6/4.3 % (D2) 6.6/4.2 % (D3) |

LC-MS/MS Parameters

LC-Parameters

| | |
|---------------------|----------------------------------------|
| Pump 1: | SPE-Buffer (0.1 - 5.0 ml/min) |
| Pump 2: | Mobile Phase (0.5 ml/min) |
| Injection volume: | 10 - 50 µl |
| Injection interval: | 3 min (4 min) |
| Switching valve: | 6-port/3-channel (order no. FK1102) |
| Column heater: | 40 °C |

MS-Parameters

| | |
|-------------|--------------------------------------|
| Ion source: | Heated Nebulizer (APCI), positive |
| MS/MS-Mode: | MRM |

Sample Processing

Precipitation:

| | |
|------------------------|------------------------------------------------|
| 150 µl mixture IS/P | 50 µl sample (calibrator, control, patient) |
|------------------------|------------------------------------------------|

Chromatogram see page 119

Ordering Information

| Order No. | Description | Quantity |
|-------------------------------------------|--------------------------------------------------------------------------------------------------------------|--------------------------------------|
| MS7100 | ClinMass® Complete Kit for 25-OH-Vitamin D2/D3 in Plasma and Serum for 1200 assays | 1 pce. |
| Kit Components (order no. MS7100): | | |
| MS7005 | Autosampler Washing Solution | 4 x MS7005 (4 x 1000 ml) |
| MS7009 | SPE-Buffer | 8 x MS7009 (8 x 1000 ml) |
| MS7010 | Mobile Phase | 4 x MS7010 (4 x 700 ml) |
| MS7012 | Internal Standard IS | 4 x MS7012 (4 x 30 ml) |
| MS7013 | Serum Calibrator Set, lyophil. (Level 0 - 3) | 4 x MS7013 (MS7013: 4 x 1 x 1 ml) |
| FK6513 | 96-Well-Plates (600 µl) | 3 x FK6513 (3 x 5 pcs.) |
| MS7021 | Precipitant P | 4 x MS7021 (4 x 15 ml) |
| | Manual | 1 pce. |
| MS7200 | ClinMass® Complete Kit for 25-OH-Vitamin D2/D3 in Plasma and Serum with Filter-Plates for 1200 assays | 1 pce. |
| Kit Components (order no. MS7200): | | |
| MS7005 | Autosampler Washing Solution | 4 x MS7005 (4 x 1000 ml) |
| MS7009 | SPE-Buffer | 8 x MS7009 (8 x 1000 ml) |
| MS7010 | Mobile Phase | 4 x MS7010 (4 x 700 ml) |
| MS7012 | Internal Standard IS | 4 x MS7012 (4 x 30 ml) |
| MS7013 | Serum Calibrator Set, lyophil. (Level 0 - 3) | 4 x MS7013 (MS7013: 4 x 1 x 1 ml) |
| FK6514 | 96-Well-Plates (300 µl) | 3 x FK6514 (3 x 5 pcs.) |
| FK6521 | 96-Well-Plates (1000 µl) | 3 x FK6521 (3 x 5 pcs.) |
| MS7021 | Precipitant P | 4 x MS7021 (4 x 15 ml) |
| | Manual | 1 pce. |
| Additional Components: | | |
| MS7014 | Optimisation Mix | 2 ml |
| MS7015 | Optimisation Mix 3-epi | 1 ml |
| Start Accessories: | | |
| MS7030 | Analytical Column with test chromatogram | 1 pce. |
| MS7035 | Analytical Column 3-epi with test chromatogram (for the additional analysis of 3-epi-25-OH-Vitamin D3) | 1 pce. |
| MS7031 | SPE-Column | 1 pce. |
| Accessories: | | |
| FK6501 | Protective sheets for 96-well-plate (PE/PP foil, 80 x 140 mm) | 50 pcs. |
| FK6514 | 96-Well-Plates (300 µl) | 5 pcs. |
| FK7340 | Sealings and sieves for order no. FK7400 | 4 pcs. each |
| FK7400 | Inline-Filter (stainless steel sieve, free of dead volume) | 1 pce. |
| ClinChek® Controls: | | |
| MS7080 | Serum Control, lyophil., Level I | 10 x 1 ml |
| MS7081 | Serum Control, lyophil., Level II | 10 x 1 ml |
| MS7082 | Serum Control, lyophil., Level I, II | 2 x 5 x 1 ml |

3.2.1 Immunosuppressants

Immunosuppressants in Whole Blood, *advanced*

► on-line Analysis

The ClinMass® Complete Kit with order no. MS1100 enables a fast on-line SPE LC-MS/MS analysis of cyclosporine A, tacrolimus, sirolimus and everolimus with an injection interval of 2 min only.

- Fast on-line analysis (injection interval: 2 min)
- No matrix effects
- 4- and 7-level calibrator set available



Test Data

| | |
|--------------------------|---------------------------------------------------------------------------|
| Linearity (up to): | 1750 µg/l (Cyc), 72 µg/l (Tcr, Srl, Evr) |
| LOD: | 0.011 µg/l (Cyc), 0.004 µg/l (Tcr), 0.073 µg/l (Srl), 0.126 µg/l (Evr) |
| LLOQ: | 0.037 µg/l (Cyc), 0.014 µg/l (Tcr), 0.244 µg/l (Srl), 0.420 µg/l (Evr) |
| Intraassay precision: | 2.5 % (Cyc), 4.6 % (Tcr), 4.8 % (Srl), 4.9 % (Evr) |
| Interassay precision: | 6.5 % (Cyc), 4.2 % (Tcr), 4.4 % (Srl), 4.3 % (Evr) |

LC-MS/MS Parameters

LC-Parameters

| | |
|---------------------|----------------------------------------|
| Pump 1: | SPE-Buffer (0.1 / 2.5 ml/min) |
| Pump 2: | Mobile Phase (0.5 / 1.0 ml/min) |
| Injection volume: | 20 - 50 µl |
| Injection interval: | 2 min |
| Switching valve: | 6-port/3-channel (order no. FK1102) |
| Column heater: | 60 °C |

MS-Parameters

| | |
|-------------|---------------|
| Ion source: | ESI, positive |
| MS/MS-Mode: | MRM |

Sample Pretreatment

Precipitation

| | | |
|-------------------------|-------------------------------|---------------------------------------------------------|
| 200 µl Precipitant P | 20 µl Internal Standard IS | 100 µl whole blood (calibrator, control, patient) |
|-------------------------|-------------------------------|---------------------------------------------------------|

1. mix and incubate (ambient temperature)
2. mix and centrifuge

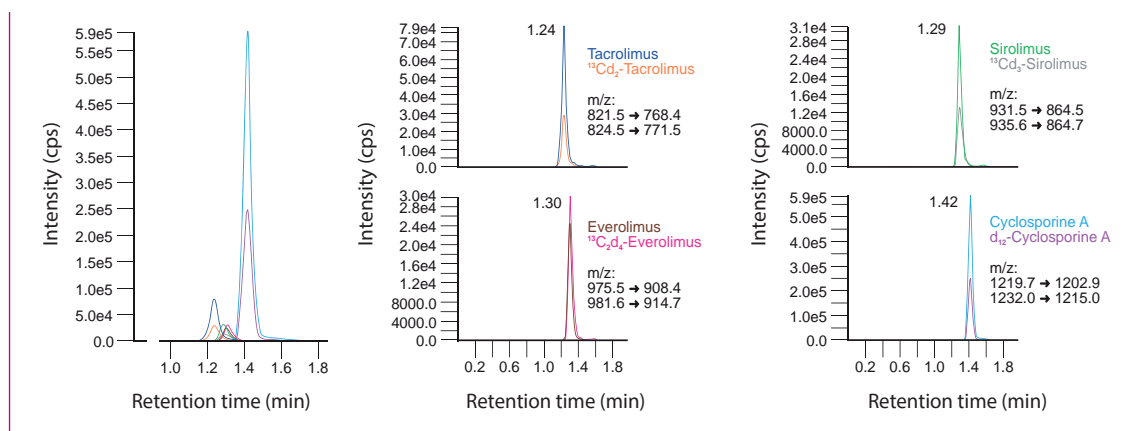


on-line Analysis

Inject 20 - 50 µl of the supernatant

3.2.1 Immunosuppressants

Chromatogram (left) and mass traces (right) of the ClinCal® Whole Blood Calibrator (order no. 9933), level 4



Ordering Information

| Order | Description | Quantity |
|-------------------------------------------|-----------------------------------------------------------------------------------------------|---------------------------|
| MS1100 | ClinMass® Complete Kit, advanced, for Immunosuppressants in Whole Blood for 400 assays | 1 pce. |
| Kit Components (order no. MS1100): | | |
| MS1005 | Autosampler Washing Solution | 1000 ml |
| MS1009 | SPE-Buffer | 2 x MS1009 (2 x 1000 ml) |
| MS1010 | Mobile Phase | 800 ml |
| MS1412 | Internal Standard IS, lyophil. | 3 x MS1412 (3 x 3 ml) |
| MS1020 | Sample Pretreatment Vials | 4 x MS1020 (4 x 100 pcs.) |
| MS1021 | Precipitant P | 80 ml |
| | Manual | 1 pce. |
| Additional Components: | | |
| MS1014 | Optimisation Mix 1, lyophil. | 2 ml |
| MS1115 | Optimisation Mix 2, lyophil. | 2 ml |
| 9028 | Whole Blood Calibrator, lyophil. (additional level for order nos. 9033 and 9933) | 2 x 2 ml |
| 9033 | Whole Blood Calibrator Set, lyophil. (Level 0 - 3) | 4 x 1 x 2 ml |
| 9933 | Whole Blood Calibrator Set, lyophil. (Level 0 - 6) | 7 x 1 x 2 ml |
| Start Accessories: | | |
| MS1030 | Analytical Column with test chromatogram | 1 pce. |
| MS1031 | SPE-Column | 1 pce. |
| MS1032 | Guard Column Holder incl. 1 Guard Column | 1 pce. |
| MS1033 | Guard Columns | 5 pcs. |
| Accessories: | | |
| FK7400 | Inline-Filter (stainless steel sieve, free of dead volume) | 1 pce. |
| FK7340 | Sealings and sieves for order no. FK7400 | 4 pcs. each |
| ClinChek® Controls: | | |
| 8830 | Whole Blood Control, lyophil., Level I | 5 x 2 ml |
| 8831 | Whole Blood Control, lyophil., Level II | 5 x 2 ml |
| 8832 | Whole Blood Control, lyophil., Level III | 5 x 2 ml |
| 8833 | Whole Blood Control, lyophil., Level I, II, III | 3 x 2 x 2 ml |
| 8903 | Whole Blood Control, lyophil., Level IV, V | 2 x 2 x 2 ml |

3.2.1 Immunosuppressants

Immunosuppressants in Whole Blood, *advanced*

- ▶ automated on-line Analysis
- ▶ automated on-line Analysis with Filter-Plates

The ClinMass® Complete Kits with order nos. MS1200 and MS1300 enable fast on-line SPE LC-MS/MS analysis of cyclosporine A, tacrolimus, sirolimus and everolimus with an injection interval of 2 min only. In order to meet laboratory demands in high sample throughput for Immunosuppressants RECIPE has developed a fully automated sample preparation kit for many liquid handling devices with the option to use 96-well filter plates as well.

- Fully automated sample preparation
- Fast on-line analysis (injection interval: 2 min)
- No matrix effects
- 4- and 7-level calibrator set available



Test Data

| | |
|--------------------------|---------------------------------------------------------------------------|
| Linearity (up to): | 1750 µg/l (Cyc), 72 µg/l (Tcr, Srl, Evr) |
| LOD: | 0.011 µg/l (Cyc), 0.004 µg/l (Tcr), 0.073 µg/l (Srl), 0.126 µg/l (Evr) |
| LLOQ: | 0.037 µg/l (Cyc), 0.014 µg/l (Tcr), 0.244 µg/l (Srl), 0.420 µg/l (Evr) |
| Intraassay precision: | 2.5 % (Cyc), 4.6 % (Tcr), 4.8 % (Srl), 4.9 % (Evr) |
| Interassay precision: | 6.5 % (Cyc), 4.2 % (Tcr), 4.4 % (Srl), 4.3 % (Evr) |

LC-MS/MS Parameters

LC-Parameters

| | |
|---------------------|----------------------------------------|
| Pump 1: | SPE-Buffer (0.1 / 2.5 ml/min) |
| Pump 2: | Mobile Phase (0.5 / 1.0 ml/min) |
| Injection volume: | 20 - 50 µl |
| Injection interval: | 2 min |
| Switching valve: | 6-port/3-channel (order no. FK1102) |
| Column heater: | 60 °C |

MS-Parameters

| | |
|-------------|---------------|
| Ion source: | ESI, positive |
| MS/MS-Mode: | MRM |

Sample Processing

Precipitation:

| | |
|------------------------|------------------------------------------------|
| 150 µl mixture IS/P | 50 µl sample (calibrator, control, patient) |
|------------------------|------------------------------------------------|

Chromatogram see page 123

Ordering Information

| Order No. | Description | Quantity |
|-------------------------------------------|--------------------------------------------------------------------------------------------------------------------------|--------------------------|
| MS1200 | ClinMass® Complete Kit, <i>advanced</i>, for Immunosuppressants in Whole Blood for 1200 assays | 1 pce. |
| Kit Components (order no. MS1200): | | |
| MS1005 | Autosampler Washing Solution | 3 x MS1005 (3 x 1000ml) |
| MS1009 | SPE-Buffer | 6 x MS1009 (6 x 1000 ml) |
| MS1010 | Mobile Phase | 3 x MS1010 (3 x 800 ml) |
| MS1412 | Internal Standard IS, lyophil. | 9 x MS1412 (9 x 3 ml) |
| FK6511 | 96-Well Plates (1200 µl) | 3 x FK6511 (3 x 5 pcs.) |
| MS1021 | Precipitant P | 3 x MS1021 (3 x 80 ml) |
| | Manual | 1pce. |
| MS1300 | ClinMass® Complete Kit, <i>advanced</i>, for Immunosuppressants in Whole Blood with Filter-Plates for 1200 assays | 1 pce. |
| Kit Components (order no. MS1300): | | |
| MS1005 | Autosampler Washing Solution | 3 x MS1005 (3 x 1000 ml) |
| MS1009 | SPE-Buffer | 6 x MS1009 (6 x 1000 ml) |
| MS1010 | Mobile Phase | 3 x MS1010 (3 x 800 ml) |
| MS1412 | Internal Standard IS, lyophil. | 9 x MS1412 (9 x 3 ml) |
| FK6514 | 96-Well-Plates (300 µl) | 3 x FK6514 (3 x 5 pcs.) |
| FK6521 | 96-Well-Filter-Plates (1000 µl) | 3 x FK6521 (3 x 5 pcs.) |
| MS1021 | Precipitant P | 3 x MS1021 (3 x 80 ml) |
| | Manual | 1 pce. |
| Additional Components: | | |
| MS1014 | Optimisation Mix 1, lyophil. | 2 ml |
| MS1115 | Optimisation Mix 2, lyophil. | 2 ml |
| 9028 | Whole Blood Calibrator, lyophil. (additional level for order nos. 9033 and 9933) | 2 x 2 ml |
| 9033 | Whole Blood Calibrator Set, lyophil. (Level 0 - 3) | 4 x 1 x 2 ml |
| 9933 | Whole Blood Calibrator Set, lyophil. (Level 0 - 6) | 7 x 1 x 2 ml |
| Start Accessories: | | |
| MS1030 | Analytical Column with test chromatogram | 1 pce. |
| MS1031 | SPE-Column | 1 pce. |
| MS1032 | Guard Column Holder incl. 1 Guard Column | 1 pce. |
| MS1033 | Guard Columns | 5 pcs. |
| Accessories: | | |
| FK6501 | Protective Sheets for 96-Well Plate (PE/PP foil, 80 x 140 mm) | 50 pcs. |
| FK6514 | 96-Well Plates (300 µl) | 5 pcs. |
| FK7400 | Inline-Filter (stainless steel sieve, free of dead volume) | 1 pce. |
| FK7340 | Sealings and sieves for order no. FK7400 | 4 pcs. each |
| ClinChek® Controls: | | |
| 8830 | Whole Blood Control, lyophil., Level I | 5 x 2 ml |
| 8831 | Whole Blood Control, lyophil., Level II | 5 x 2 ml |
| 8832 | Whole Blood Control, lyophil., Level III | 5 x 2 ml |
| 8833 | Whole Blood Control, lyophil., Level I, II, III | 3 x 2 x 2 ml |
| 8903 | Whole Blood Control, lyophil., Level IV, V | 2 x 2 x 2 ml |

Antidepressants in Serum / Plasma

In addition to the classical TCAs a variety of next generation antidepressants (ADP) is available for the treatment of depressions, such as selective serotonin and norepinephrine reuptake inhibitors (SSRIs, SNRIs, NRIs) and TeCAs.

The ClinMass® Add-on Set for Antidepressants (order no. MS9400) contains all analyte specific components required for the quantification of 36 different ADPs and metabolites.

The ClinMass® TDM Platform (order no. MS9000) contains the components needed for sample preparation and LC-MS/MS analysis. It can be used with all ClinMass® Add-on Sets of the TDM Kit System (BZP, TCA, ...). The analytical column is suitable for the whole analyte panel (155 compounds).

- Simple and timesaving sample preparation
- Flexible and fast LC-MS/MS Analysis (3.7 min) extended to 36 substances
- IS contains 28 isotope-labeled analytes



Test Data

Test data are available on request.

LC-MS/MS Parameters

LC-Parameters

Binary Gradient

Pump: Mobile Phases A/B
(0.7 ml/min)

Injection volume: 1 - 10 µl*

* depending on the sensitivity of the mass spectrometer

Injection interval: 3.7 min

Column heater: 40 °C

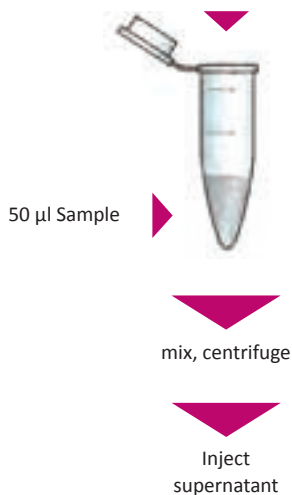
MS-Parameters

Ion source: ESI, positive

MS/MS mode: MRM

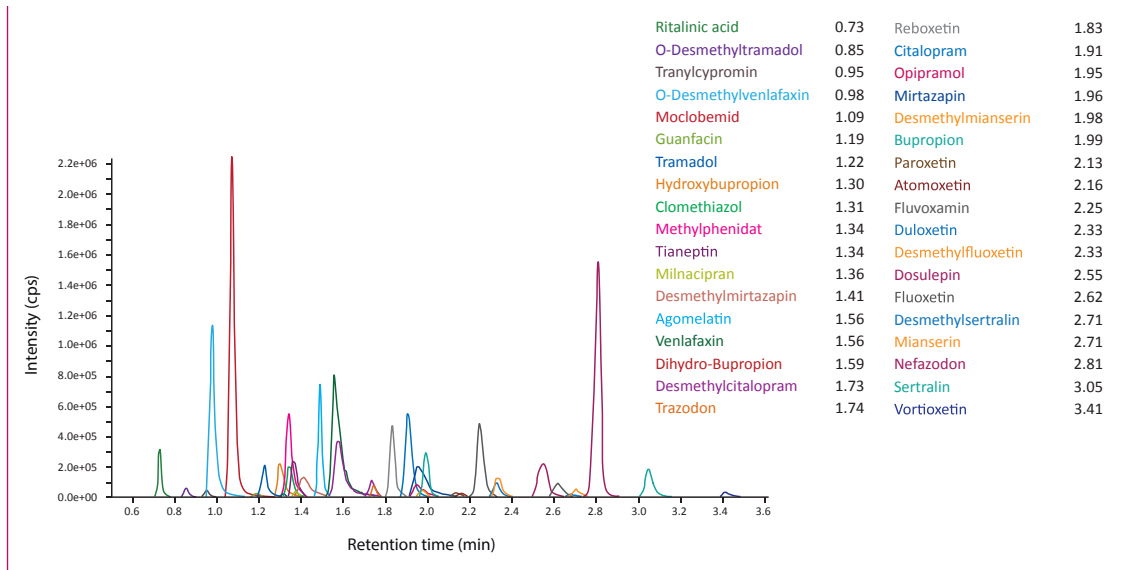
Sample Preparation

100 µl Precipitant P (contains IS)*



* Reconstitution of IS (order no. MS9412) with 5 ml Precipitant P (order no. MS9021)

Chromatogram of the ClinCal® Serum Calibrator, Level 2 (order no. MS9413)



*erythro- and threo-Dihydro-Bupropion can be separated by a modified gradient in an extra run

Ordering Information

| Order No. | Description | Quantity |
|-------------------------------------------|----------------------------------------------------------------------------------|---------------------------|
| MS9000 | ClinMass® TDM Platform for 400 assays | 1 pce. |
| Kit Components (order no. MS9000): | | |
| MS9005 | Autosampler Washing Solution | 1000 ml |
| MS9007 | Mobile Phase A | 2 x MS9007 (2 x 1000 ml) |
| MS9008 | Mobile Phase B | 1000 ml |
| MS9020 | Sample Preparation Vials | 4 x MS9020 (4 x 100 pcs.) |
| MS9021 | Precipitant P | 2 x MS9021 (2 x 25 ml) |
| Start Accessories: | | |
| MS9030 | Analytical Column with test chromatogram | 1 pce. |
| MS9032 | Prefilter | 1 pce. |
| Accessories: | | |
| MS9022 | Diluting Solution D | 50 ml |
| MS9400 | ClinMass® Add-on Set for Antidepressants in Serum / Plasma for 200 assays | 1 pce. |
| Kit Components (order no. MS9400): | | |
| MS9412 | Internal Standard IS, lyophil. | 5 x 5 ml |
| MS9413 | Serum Calibrator Set, lyophil. (Level 0 - 3) | 4 x 1 x 1 ml |
| | Manual | 1 pce. |
| Start Accessories: | | |
| MS9414 | Optimisation Mix, lyophil. | 2 x 1 x 2 ml |
| ClinChek® Controls: | | |
| MS9482 | Serum Control, lyophil., Level I, II | 2 x 5 x 1 ml |

Antiepileptic Drugs in Serum / Plasma

Antiepileptic Drugs (AED) are used for the treatment of epilepsy, a chronic neurological disorder, which is characterised by recurrent epileptic seizures.

The ClinMass® Add-on Set for Antiepileptic Drugs (order no. MS9200) contains all analyte specific components required for the quantification of 27 different AEDs and metabolites.

The ClinMass® TDM Platform (order no. MS9000) contains the components needed for sample preparation and LC-MS/MS analysis. It can be used with all ClinMass® Add-on Sets of the TDM Kit System. The analytical column is suitable for the whole analyte panel (155 compounds).

- Simple and timesaving sample preparation
- Flexible and fast LC-MS/MS Analysis (4.5 min)



Test Data

Test data are available on request.

LC-MS/MS Parameters

LC-Parameters

Binary Gradient

Pump: Mobile Phases A/B
(0.6 ml/min)

Injection volume: 1 - 10 μ l*

* depending on the sensitivity of the mass spectrometer

Injection interval: 4.5 min

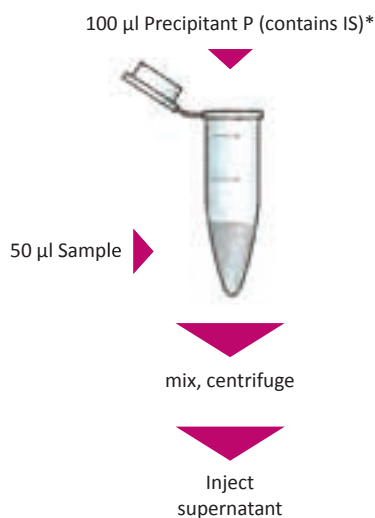
Column heater: 40 °C

MS-Parameters

Ion source: ESI, positive / negative

MS/MS mode: MRM

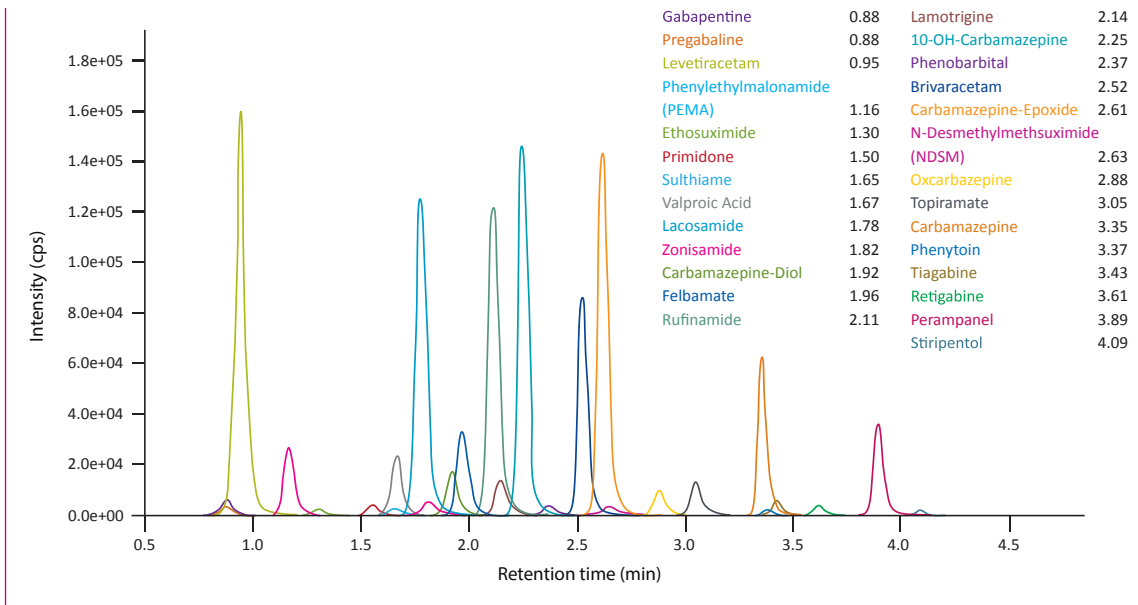
Sample Preparation



One step!

* Reconstitution of IS (order no. MS9212) with 5 ml Precipitant P (order no. MS9021)

Chromatogram of the ClinCal® Serum Calibrator, Level 2 (order no. MS9213)



Ordering Information

| Order No. | Description | Quantity |
|-------------------------------------------|--------------------------------------------------------------------------------------|---------------------------|
| MS9000 | ClinMass® TDM Platform for 400 assays | 1 pce. |
| Kit Components (order no. MS9000): | | |
| MS9005 | Autosampler Washing Solution | 1000 ml |
| MS9007 | Mobile Phase A | 2 x MS9007 (2 x 1000 ml) |
| MS9008 | Mobile Phase B | 1000 ml |
| MS9020 | Sample Preparation Vials | 4 x MS9020 (4 x 100 pcs.) |
| MS9021 | Precipitant P | 2 x MS9021 (2 x 25 ml) |
| Start Accessories: | | |
| MS9030 | Analytical Column with test chromatogram | 1 pce. |
| MS9032 | Prefilter | 1 pce. |
| Accessories: | | |
| MS9022 | Diluting Solution D | 50 ml |
| MS9200 | ClinMass® Add-on Set for Antiepileptic Drugs in Serum / Plasma for 200 assays | 1 pce. |
| Kit Components (order no. MS9200): | | |
| MS9212 | Internal Standard IS, lyophil. | 5 x 5 ml |
| MS9213 | Serum Calibrator Set, lyophil. (Level 0 - 3) | 4 x 1 x 1 ml |
| | Manual | 1 pce. |
| Start Accessories: | | |
| MS9214 | Optimisation Mix, lyophil. | 5 x 1 x 2 ml |
| ClinChek® Controls: | | |
| MS9282 | Serum Control, lyophil., Level I, II | 2 x 5 x 1 ml |

Antimycotics in Serum / Plasma

Invasive fungal infections, predominantly aspergillosis and candidiasis are the most important causes of morbidity and mortality in immunocompromised patients. Antimycotics are used for the treatment and prophylaxis of fungal infections. Antifungal drugs show large intra- and interindividual variabilities in pharmacokinetics, thus, the accurate measurement of the individual drug concentration in serum/plasma is essential for therapy control and success.

The ClinMass® Add-On Set for Antimycotics (order no. MS9600) contains all analyte specific components required for the determination of 8 drugs and metabolites.

- Covers 8 antimycotics
- Isotopically labeled Internal Standards



Test Data

Test data are available on request.

LC-MS/MS Parameters

LC-Parameters

Binary Gradient

Pump: Mobile Phases A/B
(0.6 ml/min)

Injection volume: 1 – 10 μ l

Injection interval: 3.5 min

Column heater: 40 °C

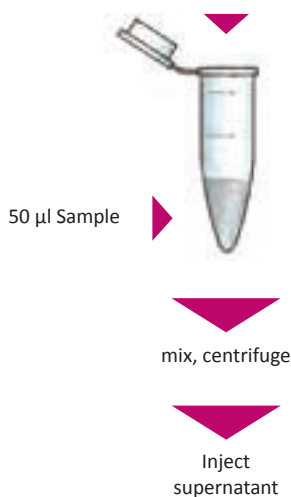
MS-Parameters

Ion source: ESI

MS/MS mode: MRM

Sample Preparation

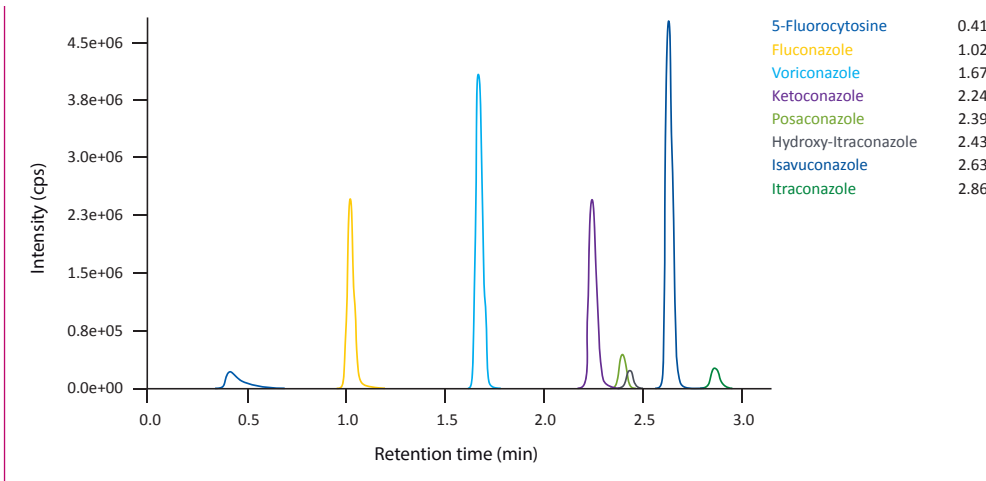
100 μ l Precipitant P (contains IS)*



One step!

* Reconstitution of IS (order no. MS9612) with 5 ml Precipitant P (order no. MS9021)

Chromatogram of the ClinCal® Serum Calibrator, Level 2 (order no. MS9613)



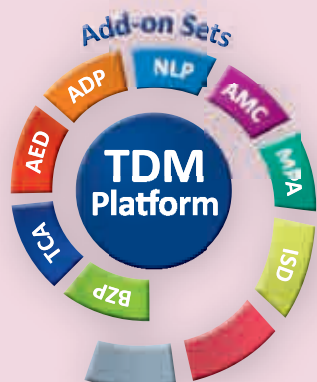
Ordering Information

| Order No. | Description | Quantity |
|-------------------------------------------|-------------------------------------------------------------------------------|---------------------------|
| MS9000 | ClinMass® TDM Platform for 400 assays | 1 pce. |
| Kit Components (order no. MS9000): | | |
| MS9005 | Autosampler Washing Solution | 1000 ml |
| MS9007 | Mobile Phase A | 2 x MS9007 (2x 1000 ml) |
| MS9008 | Mobile Phase B | 1000 ml |
| MS9020 | Sample Preparation Vials | 4 x MS9020 (4 x 100 pcs.) |
| MS9021 | Precipitant P | 2 x MS9021 (2 x 25 ml) |
| Start Accessories: | | |
| MS9030 | Analytical Column with test chromatogram | 1 pce. |
| MS9032 | Prefilter | 1 pce. |
| Accessories: | | |
| MS9022 | Diluting Solution D | 50 ml |
| MS9600 | ClinMass® Add-on Set for Antimycotics in Serum / Plasma for 200 assays | 1 pce. |
| Kit Components (order no. MS9600): | | |
| MS9612 | Internal Standard IS, lyophil. | 5 x 5 ml |
| MS9613 | Serum Calibrator Set, lyophil. (Level 0 - 3) | 4 x 1 x 1 ml |
| | Manual | 1 pce. |
| Start Accessories: | | |
| MS9614 | Optimisation Mix, lyophil. | 2 ml |
| ClinChek® Controls: | | |
| MS9682 | Serum Control, lyophil., Level I, II | 2 x 5 x 1 ml |

Benzodiazepines in Serum / Plasma

Benzodiazepines (BZP) are a group of psychoactive drugs with a broad range of therapeutic effects and belong to the most frequently prescribed drugs all over the world. The ClinMass® Add-on Set for Benzodiazepines (order no. MS9500) contains all analyte specific components required for the quantification of 36 different drugs and metabolites. The ClinMass® TDM Platform (order no. MS9000) contains the components needed for sample preparation and LC-MS/MS analysis. It can be used with all ClinMass® Add-on Sets of the TDM Kit System (BZP, TCA, ...). The analytical column is suitable for the whole analyte panel (155 compounds).

- One step sample preparation
- Flexible and fast LC-MS/MS Analysis (6.8 min) of 36 Benzodiazepines
- Z-drugs included



Test Data

Test data are available on request.

LC-MS/MS Parameters

LC-Parameters

Binary Gradient

Pump: Mobile Phases A/B
(0.6 ml/min)

Injection volume: 1 - 10 µl*

* depending on the sensitivity of the mass spectrometer

Injection interval: 6.8 min

Column heater: 40 °C

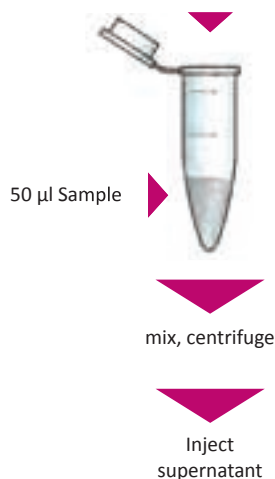
MS-Parameters

Ion source: ESI, positive

MS/MS-Mode: MRM

Sample Preparation

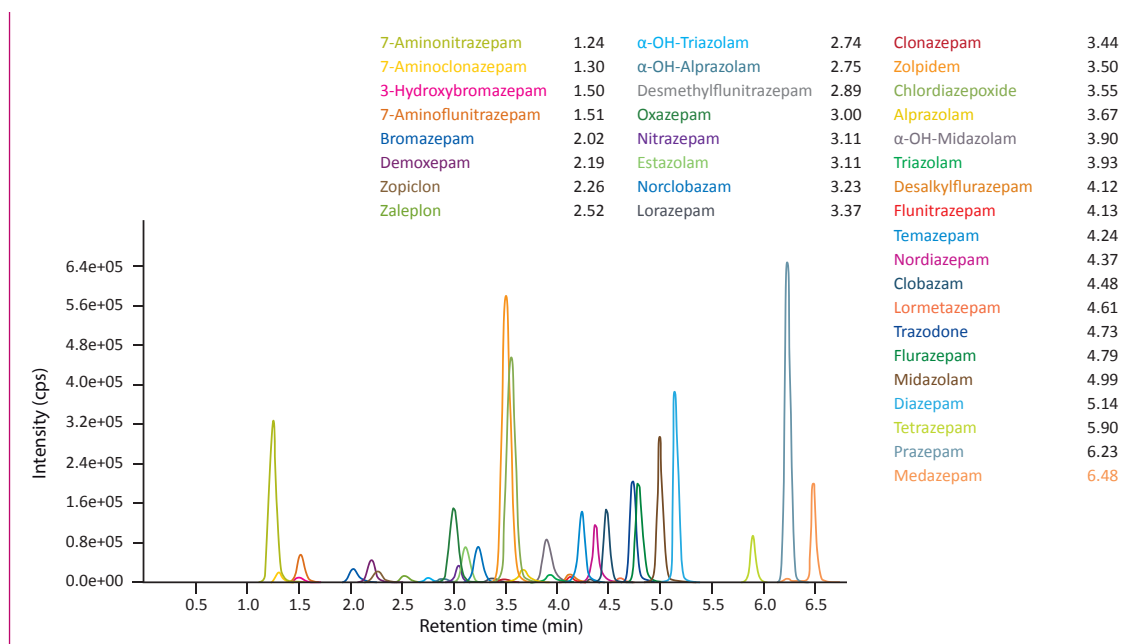
100 µl Precipitant P (contains IS)*



One step!

* Reconstitution of IS (order no. MS9512) with 5 ml Precipitant P (order no. MS9021)

Chromatogram of the ClinCal® Serum Calibrator, Level 2 (order no. MS6013)



Ordering Information

| Order No. | Description | Quantity |
|-------------------------------------------|----------------------------------------------------------------------------------|---------------------------|
| MS9000 | ClinMass® TDM Platform for 400 assays | 1 pce. |
| Kit Components (order no. MS9000): | | |
| MS9005 | Autosampler Washing Solution | 1000 ml |
| MS9007 | Mobile Phase A | 2 x MS9007 (2 x 1000 ml) |
| MS9008 | Mobile Phase B | 1000 ml |
| MS9020 | Sample Preparation Vials | 4 x MS9020 (4 x 100 pcs.) |
| MS9021 | Precipitant P | 2 x MS9021 (2 x 25 ml) |
| Start Accessories: | | |
| MS9030 | Analytical Column with test chromatogram | 1 pce. |
| MS9032 | Prefilter | 1 pce. |
| Accessories: | | |
| MS9022 | Diluting Solution D | 50 ml |
| MS9500 | ClinMass® Add-on Set for Benzodiazepines in Serum / Plasma for 200 assays | 1 pce. |
| Kit Components (order no. MS9500): | | |
| MS9512 | Internal Standard IS, lyophil. | 5 x 5 ml |
| MS6013 | Serum Calibrator Set, lyophil. (Level 0 - 3) | 4 x 1 x 1 ml |
| | Manual | 1 pce. |
| Start Accessories: | | |
| MS6015 - | Optimisation Mix 1 - 5, lyophil. | 2 ml each |
| MS6019 | | |
| ClinChek® Controls: | | |
| MS6082 | Serum Control, lyophil., Level I, II | 2 x 5 x 1 ml |

Immunosuppressants in Whole Blood

The new Add-on Set (order no. MS99200) for the TDM Platform provides the analysis of cyclosporine A, tacrolimus, everolimus and sirolimus in whole blood with an injection interval of 1.9 min only.

The ClinMass® TDM Platform (order no. MS9000A) contains the components needed for sample preparation and LC-MS/MS analysis. The analytical column is suitable for the whole analyte panel (155 compounds).

- Immunosuppressants now available for ClinMass® TDM Platform
- Flexible and fast LC-MS/MS Analysis (1.9 min)



Test Data

| | |
|-----------------------|----------------------------------------------------------------------------|
| Linearity (up to): | 2228 µg/l (Cyc), 80 – 93 µg/l (Tcr, Srl, Evr) |
| LOD: | 2.92 µg/l (Cyc), 0.144 µg/l (Tcr) 0.101 µg/l (Srl) 0.0967 µg/l (Evr) |
| LLOQ: | 8.77 µg/l (Cyc), 0.433 µg/l (Tcr) 0.302 µg/l (Srl), 0.290 µg/l (Evr) |
| Intraassay precision: | 5.6 % (Cyc), 6.0 % (Tcr) 5.3 % (Srl), 4.5 % (Evr) |
| Interassay precision: | 5.4 % (Cyc), 5.1 % (Tcr) 8.4 % (Srl), 9.1 % (Evr) |

LC-MS/MS Parameters

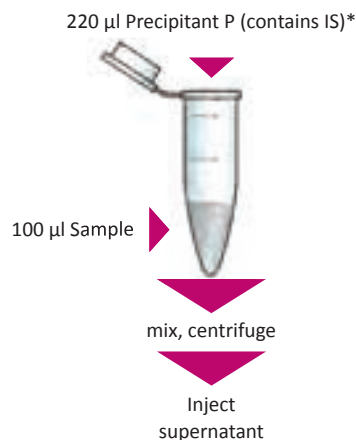
LC-Parameters

| | |
|---------------------------------------------------------|-----------------------------------|
| Binary gradient pump: | Mobile Phases A/B (0.9 ml/min) |
| Injection volume: | 5 - 50 µl* |
| * depending on the sensitivity of the mass spectrometer | |
| Injection interval: | 1.9 min |
| Column heater: | 70 °C |

MS-Parameters

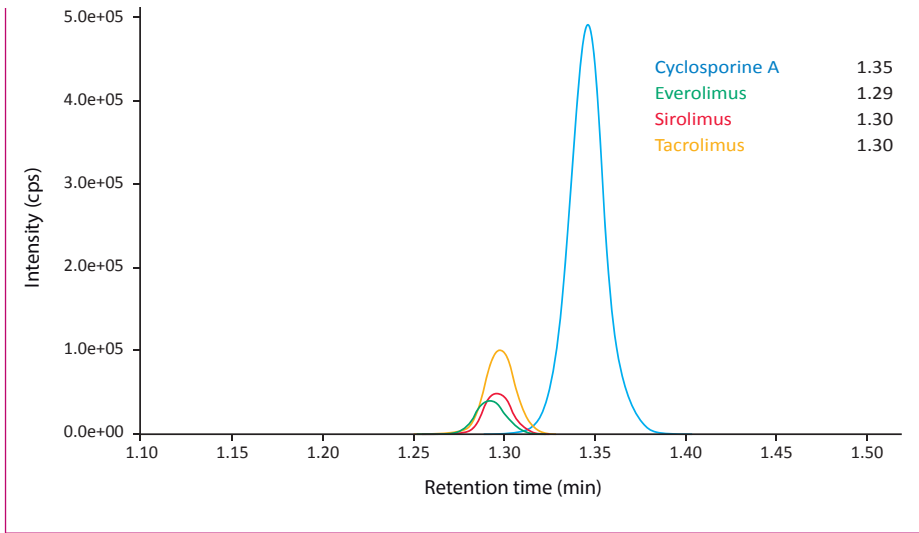
| | |
|-------------|---------------|
| Ion source: | ESI, positive |
| MS/MS-Mode: | MRM |

Sample Preparation



* Mixture of IS (order no. MS1412) with Precipitant P (order no. MS1021) with a ratio of 1 : 10

Chromatogram of the ClinCal® Whole Blood Calibrator, Level 2 (order no. 9928)



Ordering Information

| Order No. | Description | Quantity |
|--------------------------------------------|----------------------------------------------------------------------------------|-----------------------|
| MS9000A | ClinMass® TDM Platform for 400 assays | 1 pce. |
| Kit Components (order no. MS9000A): | | |
| MS9005 | Autosampler Washing Solution | 1000 ml |
| MS9007 | Mobile Phase A | 1000 ml |
| MS9008 | Mobile Phase B | 1000 ml |
| MS9020 | Sample Preparation Vials | 100 pcs. |
| MS1021 | Precipitant P | 80 ml |
| Start Accessories: | | |
| MS9030 | Analytical Column with test chromatogram | 1 pce. |
| MS9032 | Prefilter | 1 pce. |
| MS99200 | ClinMass® Add-on Set for Immunosuppressants in Whole Blood for 200 assays | 1 pce. |
| Kit Components (order no. MS99200): | | |
| MS1412 | Internal Standard IS, lyophil. | 2 x MS1412 (2 x 3 ml) |
| 9028 | Whole Blood Calibrator, lyophil. (additional level for order nos. 9033 and 9933) | 2 x 2 ml |
| | Manual | 1 pce. |
| Start Accessories: | | |
| MS1014 | Optimisation Mix 1, lyophil. | 2 ml |
| MS1115 | Optimisation Mix 2, lyophil. | 2 ml |
| Accessories: | | |
| 9033 | Whole Blood Calibrator Set, lyophil. (Level 0 - 3) | 4 x 1 x 2 ml |
| 9933 | Whole Blood Calibrator Set, lyophil. (Level 0 - 6) | 7 x 1 x 2 ml |
| ClinChek® Controls: | | |
| 8830 | Whole Blood Control, lyophil., Level I | 5 x 2 ml |
| 8831 | Whole Blood Control, lyophil., Level II | 5 x 2 ml |
| 8832 | Whole Blood Control, lyophil., Level III | 5 x 2 ml |
| 8833 | Whole Blood Control, lyophil., Level I, II, III | 3 x 2 x 2 ml |
| 8903 | Whole Blood Control, lyophil., Level IV, V | 2 x 2 x 2 ml |

Mycophenolic Acid in Serum / Plasma

Mycophenolic Acid (MPA) is widely used in immunosuppressive regimens after heart, liver and especially kidney transplantation to prevent organ rejection as well as for treatment of autoimmune diseases.

The ClinMass Add-On Set für Mycophenolic Acid (order no. MS99100) contains all analyte specific components required for the determination of the immunosuppressive drug. Additionally, RECIPE's analytical method ensures an adequate chromatographic separation from the glucuronide metabolite MPAG. Thus false positive MPA values caused by ion-source fragmentation of MPAG are avoided.

The ClinMass® TDM-Plattform (order no. MS9000) contains all necessary components for sample preparation and LC-MS/MS analysis and can be used with all ClinMass® Add-On sets of the TDM Kit system in combination with the unique analytical column for all TDM panels.

- Simple and timesaving sample preparation
- Isotopically labelled Internal Standard



Test Data

Test data are available on request.

LC-MS/MS Parameters

LC-Parameters

Binary Gradient

Pump: Mobile Phases A/B
(0.5 ml/min)

Injection volume: 5 – 50 µl

Injection interval: 1.9 min

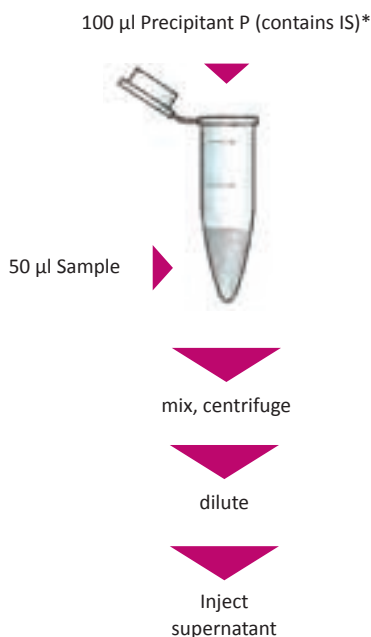
Column heater: 40 °C

MS-Parameters

Ion source: ESI

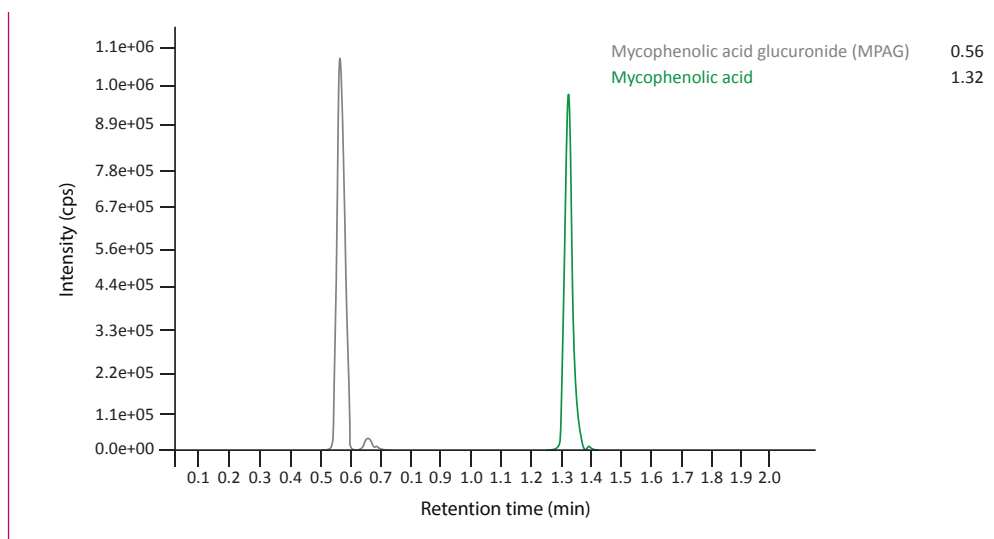
MS/MS mode: MRM

Sample Preparation



* Reconstitution of IS (order no. MS99112) with 5 ml Precipitant P (order no. MS9021)

Chromatogram of the ClinCal® Plasma Calibrator, Level 2 (order no. MS99113), spiked with MPAG



Ordering Information

| Order No. | Description | Quantity |
|--------------------------------------------|------------------------------------------------------------------------------------|---------------------------|
| MS9000 | ClinMass® TDM Platform for 400 assays | 1 pce. |
| Kit Components (order no. MS9000): | | |
| MS9005 | Autosampler Washing Solution | 1000 ml |
| MS9007 | Mobile Phase A | 2 x MS9007 (2 x 1000 ml) |
| MS9008 | Mobile Phase B | 1000 ml |
| MS9020 | Sample Preparation Vials | 4 x MS9020 (4 x 100 pcs.) |
| MS9021 | Precipitant P | 2 x MS9021 (2 x 25 ml) |
| Start Accessories: | | |
| MS9030 | Analytical Column | 1 pce. |
| MS9032 | Prefilter | 1 pce. |
| Accessory: | | |
| MS9022 | Diluting Solution D | 50 ml |
| MS99100 | ClinMass® Add-on Set for Mycophenolic Acid in Serum / Plasma for 200 assays | 1 pce. |
| Kit Components (order no. MS99100): | | |
| MS99112 | Internal Standard IS, lyophil. | 5 x 5 ml |
| MS99113 | Serum Calibrator Set, lyophil., Level 0 - 3 | 4 x 1 x 1 ml |
| MS9022 | Diluting Solution D | 2 x MS9022 (2 x 50 ml) |
| Start Accessories: | | |
| MS99114 | Optimisation Mix, lyophil. | 2 ml |
| ClinChek® Controls: | | |
| MS99183 | Plasma Control, lyophil., Level I, II, III | 3 x 3 x 1 ml |

Neuroleptics in Serum/ Plasma

Neuroleptics belong to the class of psychoactive drugs and are administered in the therapy of psychoses, in particular the symptomatic treatment of schizophrenia.

The ClinMass® Add-On Set for Neuroleptics (order no. MS9300) contains all analyte-specific components for determination of 28 different neuroleptics.

The ClinMass® TDM Platform (order no. MS9000) contains the components needed for sample preparation and LC-MS/MS analysis. It can be used with all ClinMass® Add-on Sets of the TDM Kit System (BZP, TCA, ...). The analytical column is suitable for the whole analyte panel (155 compounds).

- Simple and timesaving sample preparation
- Flexible and fast LC-MS/MS Analysis (6.0 min)
- IS contains 28 isotope labelled analytes



Test Data

Test data are available on request.

LC-MS/MS Parameters

LC-Parameters

Binary HPLC

pump: Mobile Phases A / B
(0.65 ml/min)

Injection volume: 1 - 10 μ l

Injection interval: 6.0 min

Column heater: 40 °C

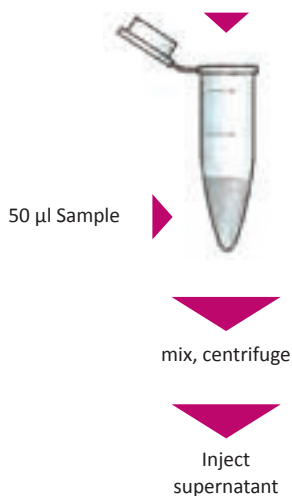
MS-Parameters

Ion source: ESI

MS/MS mode: MRM

Sample Preparation

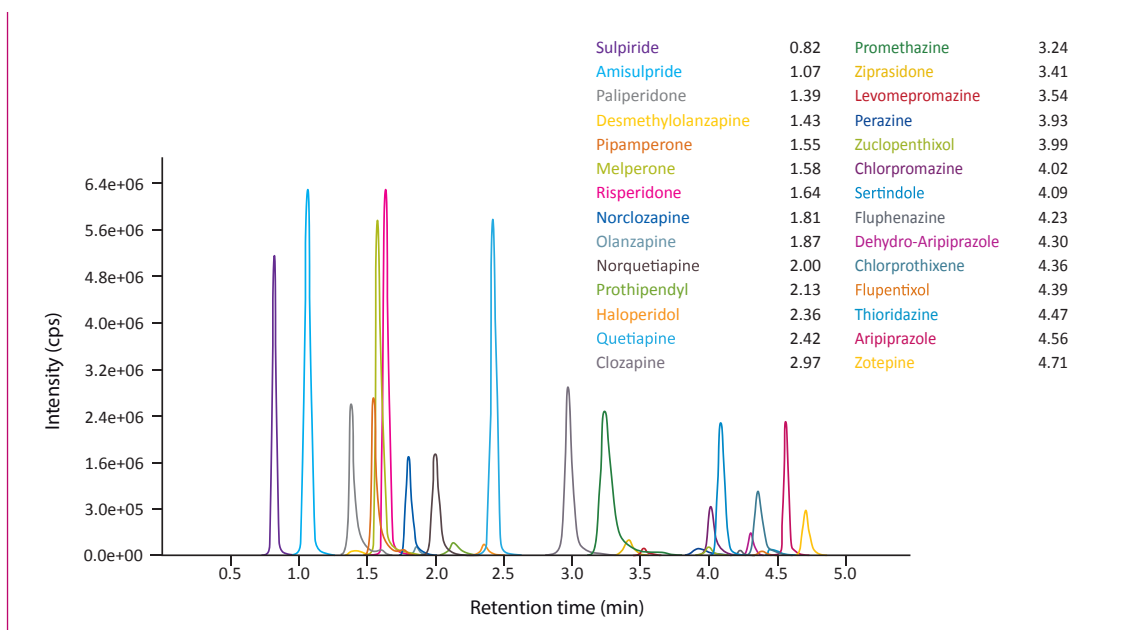
100 μ l Precipitant P (contains IS)*



One step!

* Reconstitution of IS (order no. MS9312) with 5 ml Precipitant P (order no. MS9021)

Chromatogram of the ClinCal® Serum Calibrator, Level 2 (order no. MS9313)



Ordering Information

| Order No. | Description | Quantity |
|-------------------------------------------|-------------------------------------------------------------------------------|---------------------------|
| MS9000 | ClinMass® TDM Platform for 400 assays | 1 pce. |
| Kit Components (order no. MS9000): | | |
| MS9005 | Autosampler Washing Solution | 1000 ml |
| MS9007 | Mobile Phase A | 2 x MS9007 (2x 1000 ml) |
| MS9008 | Mobile Phase B | 1000 ml |
| MS9020 | Sample Preparation Vials | 4 x MS9020 (4 x 100 pcs.) |
| MS9021 | Precipitant P | 2 x MS9021 (2 x 25 ml) |
| Start Accessories: | | |
| MS9030 | Analytical Column with test chromatogram | 1 pce. |
| MS9032 | Prefilter | 1 pce. |
| Accessories: | | |
| MS9022 | Diluting Solution D | 50 ml |
| MS9300 | ClinMass® Add-on Set for Neuroleptics in Serum / Plasma for 200 assays | 1 pce. |
| Kit Components (order no. MS9300): | | |
| MS9312 | Internal Standard IS, lyophil. | 5 x 5 ml |
| MS9313 | Serum Calibrator Set, lyophil. (Level 0 - 3) | 4 x 1 x 1 ml |
| | Manual | |
| Start Accessories: | | |
| MS9314 | Optimisation Mix, lyophil. | 2 x 1 x 2 ml |
| ClinChek® Controls: | | |
| MS9382 | Serum Control, lyophil., Level I, II | 2 x 5 x 1 ml |

Tricyclic Antidepressants in Serum/Plasma

Tricyclic antidepressants (TCA) are a group of psychoactive drugs which are mainly used for the therapy of endogenous depressions, anxiety and pain management.

The ClinMass® Add-on Set for TCAs (order no. MS9100) contains all analyte specific components required for the quantification of 13 TCAs + 2 neuroleptics.

The ClinMass® TDM Platform (order no. MS9000) contains the components needed for sample preparation and LC-MS/MS analysis. It can be used with all ClinMass® Add-on Sets of the TDM Kit System (BZP, TCA, ...).

- Simple and timesaving sample preparation
- Flexible and fast LC-MS/MS Analysis (3.8 min) of 15 substances
- IS contains 12 isotope labeled analytes



Test Data

Test data are available on request.

LC-MS/MS Parameters

LC-Parameters

Binary Gradient

Pump: Mobile Phases A/B
(0.8 ml/min)

Injection volume: 1 - 10 µl*

* depending on the sensitivity of the mass spectrometer

Injection interval: 3.8 min

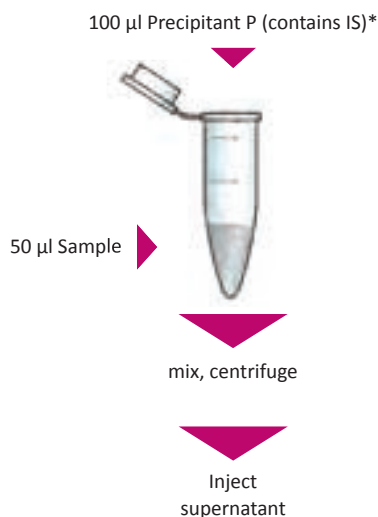
Column heater: 40 °C

MS-Parameters

Ion source: ESI, positive

MS/MS mode: MRM

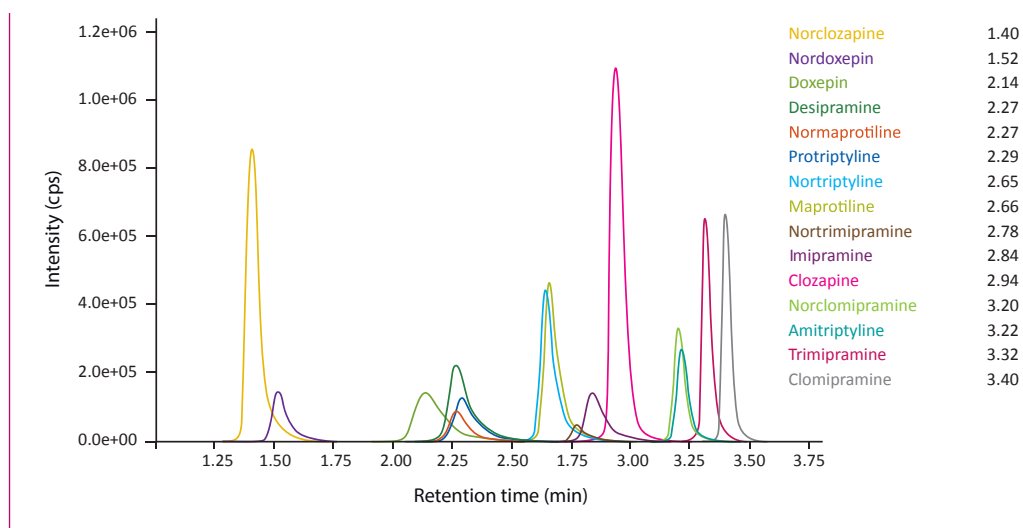
Sample Preparation



One step!

* Reconstitution of IS (order no. MS9112) with 5 ml Precipitant P (order no. MS9021)

Chromatogram of the ClinCal® Serum Calibrator, Level 2 (order no. MS9113)



Ordering Information

| Order No. | Description | Quantity |
|-------------------------------------------|--------------------------------------------------------------------------------------------|---------------------------|
| MS9000 | ClinMass® TDM Platform for 400 assays | 1 pce. |
| Kit Components (order no. MS9000): | | |
| MS9005 | Autosampler Washing Solution | 1000 ml |
| MS9007 | Mobile Phase A | 2 x MS9007 (2 x 1000 ml) |
| MS9008 | Mobile Phase B | 1000 ml |
| MS9020 | Sample Preparation Vials | 4 x MS9020 (4 x 100 pcs.) |
| MS9021 | Precipitant P | 2 x MS9021 (2 x 25 ml) |
| Start Accessories: | | |
| MS9030 | Analytical Column with test chromatogram | 1 pce. |
| MS9032 | Prefilter | 1 pce. |
| Accessories: | | |
| MS9022 | Diluting Solution D | 50 ml |
| MS9100 | ClinMass® Add-on Set for Tricyclic Antidepressants in Serum / Plasma for 200 assays | 1 pce. |
| Kit Components (order no. MS9100): | | |
| MS9112 | Internal Standard IS, lyophil. | 5 x 5 ml |
| MS9113 | Serum Calibrator Set, lyophil. (Level 0 - 3) | 4 x 1 x 1 ml |
| | Manual | 1 pce. |
| Start Accessories: | | |
| MS9114 | Optimisation Mix, lyophil. | 3 x 1 x 2 ml |
| ClinChek® Controls: | | |
| MS9182 | Serum Control, lyophil., Level I, II | 2 x 5 x 1 ml |

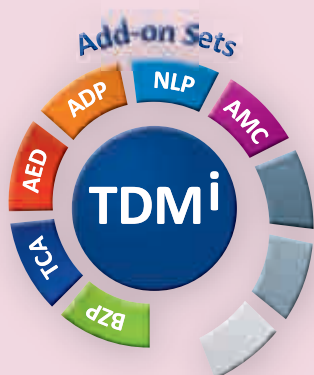
Antidepressants in Serum / Plasma

In addition to the classical TCAs a variety of newer antidepressants (ADP) is available for the treatment of depressions, such as selective serotonin and norepinephrine reuptake inhibitors (SSRIs, SNRIs, NRIs) and TCAs.

The ClinMass® Add-on Set for Antidepressants (order no. MS9450) contains all analyte specific components required for the quantification of 36 different ADPs and metabolites.

The ClinMass® TDM Platform (order no. MS9050) contains the components needed for on-line SPE LCMS/MS analysis. It can be used with all ClinMass® Add-on Sets of the "TDM Kit System, on-line". The analytical column is suitable for the whole analyte panel (147 compounds).

- Flexible and fast LC-MS/MS Analysis (4.8 min)
- IS contains 28 isotope labeled analytes



Test Data

Test data are available on request.

LC-MS/MS Parameters

LC-Parameters

Pump 1 (SPE): gradient program
(0.1 - 3.5 ml/min)

Pump 2
(Mobile Phase A, B): gradient program
(0.7 ml/min)

Injection volume: 3 - 15 µl*

* depending on the sensitivity of the mass spectrometer

Injection interval: 4.8 min

Column heater: 40 °C

MS-Parameters

Ion source: ESI, positive

MS/MS mode: MRM

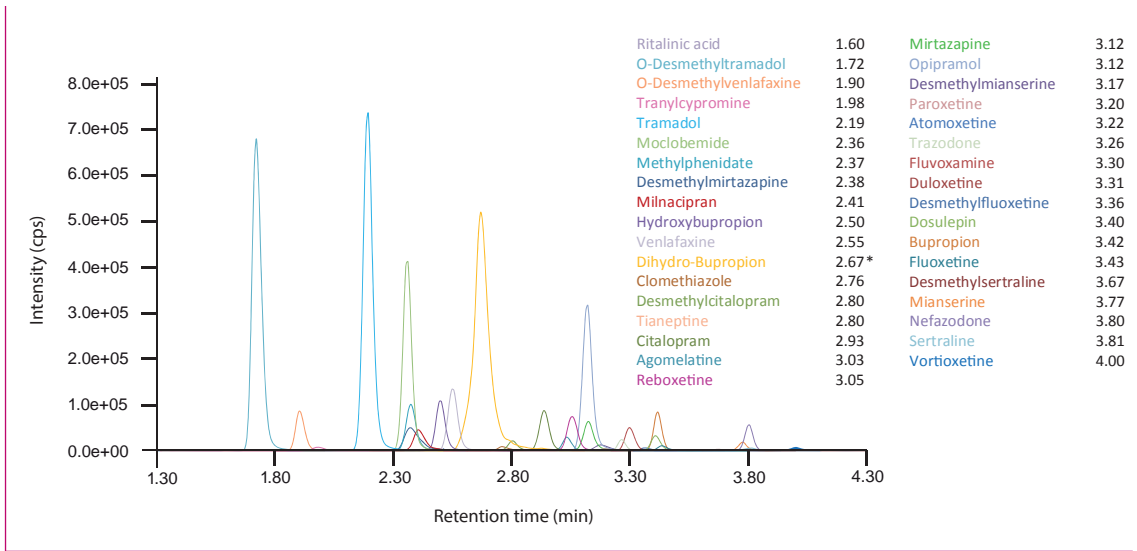
on-line SPE

Direct injection of sample and Internal Standard IS in the ratio 1:2 (autosampler).

Direct injection!

3.2.3 TDM Kit System, on-line

Chromatogram of the ClinCal® Serum Calibrator, Level 2 (order no. MS9413)



*erythro- and threo-Dihydro-Bupropion can be separated by a modified gradient in an extra run

Ordering Information

| Order No. | Description | Quantity |
|-------------------------------------------|--------------------------------------------------------------------------------------------|--------------------------|
| MS9050 | ClinMass® TDM Platform, on-line for 400 assays | 1 pce. |
| Kit Components (order no. MS9050): | | |
| MS9005 | Autosampler Washing Solution | 1000 ml |
| MS9007 | Mobile Phase A | 2 x MS9007 (2 x 1000 ml) |
| MS9008 | Mobile Phase B | 1000 ml |
| MS9059 | SPE-Buffer Load L | 2 x MS9059 (2 x 2500 ml) |
| MS9060 | SPE-Buffer Wash W | 2 x MS9060 (2 x 2500 ml) |
| MS9071 | Reconstitution Solution R | 5 ml |
| Start Accessories: | | |
| MS9035 | Analytical Column with test chromatogram | 1 pce. |
| MS9031 | SPE-Column | 1 pce. |
| MS9032 | Pre-filter | 1 pce. |
| Accessories: | | |
| MS9022 | Diluting Solution D | 50 ml |
| FK7400 | Inline-Filter (stainless steel sieve, free of dead volume) | 1 pce. |
| FK7340 | Sealings and sieves for order no. FK7400 | 4 pcs. each |
| MS9450 | ClinMass® Add-on Set, on-line, for Antidepressants in Serum / Plasma for 400 assays | 1 pce. |
| Kit Components (order no. MS9450): | | |
| MS9462 | Internal Standard IS, lyophil. | 5 ml |
| MS9413 | Serum Calibrator Set, lyophil. (Level 0 - 3) | 4 x 1 x 1 ml |
| | Manual | 1 pce. |
| Start Accessories: | | |
| MS9414 | Optimisation Mix, lyophil. | 2 x 1 x 2 ml |
| ClinChek® Controls: | | |
| MS9482 | Serum Control, lyophil., Level I, II | 2 x 5 x 1 ml |

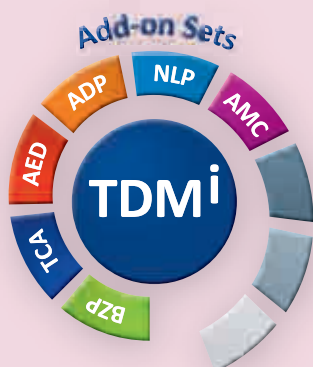
Antiepileptic Drugs in Serum / Plasma

Antiepileptic drugs (AED) are used for the treatment of epilepsy, a chronic neurological disorder, which is characterised by recurrent epileptic seizures.

The ClinMass® Add-on Set for Antiepileptic Drugs (order no. MS9250) contains all analyte specific components required for the quantification of 26 different AEDs and metabolites.

The ClinMass® TDM Platform (order no. MS9050) contains the components needed for on-line SPE LCMS/MS analysis. It can be used with all ClinMass® Add-on Sets of the “TDM Kit System, on-line” (BZP, TCA, ...). The analytical column is suitable for the whole analyte panel (147 compounds).

- No manual sample preparation needed
- Flexible and fast LC-MS/MS Analysis (7.0 min)
- IS contains 18 isotope labeled analytes



Test Data

Test data are available on request.

LC-MS/MS Parameters

LC-Parameters

Pump 1 (SPE): gradient program
(0.1 - 4 ml/min)

Pump 2
(Mobile Phase A, B): gradient program
(0.6 ml/min)

Injection volume: 3 - 15 µl*

* depending on the sensitivity of the mass spectrometer

Injection interval: 7.0 min

Column heater: 40 °C

MS-Parameters

Ion source: ESI, positive / negative

MS/MS mode: MRM

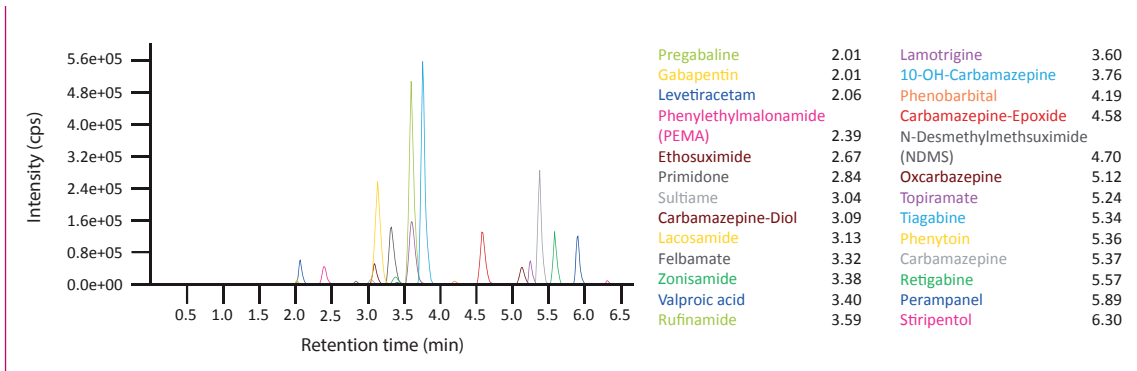
Sample Preparation

No manual sample preparation needed!
Direct injection of sample and Internal Standard IS in the ratio 1:2 (autosampler).

Direct injection!

3.2.3 TDM Kit System, on-line

Chromatogram of the ClinCal® Serum Calibrator, Level 2 (order no. MS9213)



Ordering Information

| Order No. | Description | Quantity |
|-------------------------------------------|------------------------------------------------------------------------------------------------|--------------------------|
| MS9050 | ClinMass® TDM Platform, on-line for 400 assays | 1 pce. |
| Kit Components (order no. MS9050): | | |
| MS9005 | Autosampler Washing Solution | 1000 ml |
| MS9007 | Mobile Phase A | 2 x MS9007 (2 x 1000 ml) |
| MS9008 | Mobile Phase B | 1000 ml |
| MS9059 | SPE-Buffer Load L | 2 x MS9059 (2 x 2500 ml) |
| MS9060 | SPE-Buffer Wash W | 2 x MS9060 (2 x 2500 ml) |
| MS9071 | Reconstitution Solution R | 5 ml |
| Start Accessories: | | |
| MS9035 | Analytical Column with test chromatogram | 1 pce. |
| MS9031 | SPE-Column | 1 pce. |
| MS9032 | Prefilter | 1 pce. |
| Accessories: | | |
| MS9022 | Diluting Solution D | 50 ml |
| FK7400 | Inline-Filter (stainless steel sieve, free of dead volume) | 1 pce. |
| FK7340 | Sealings and sieves for order no. FK7400 | 4 pcs. each |
| MS9250 | ClinMass® Add-on Set, on-line, for Antiepileptic Drugs in Serum / Plasma for 400 assays | 1 pce. |
| Kit Components (order no. MS9250): | | |
| MS9262 | Internal Standard IS, lyophil. | 5 ml |
| MS9213 | Serum Calibrator Set, lyophil. (Level 0 - 3) | 4 x 1 x 1 ml |
| | Manual | 1 pce. |
| Start Accessories: | | |
| MS9214 | Optimisation Mix, lyophil. | 5 x 1 x 2 ml |
| ClinChek® Controls: | | |
| MS9282 | Serum Control, lyophil., Level I, II | 2 x 5 x 1 ml |

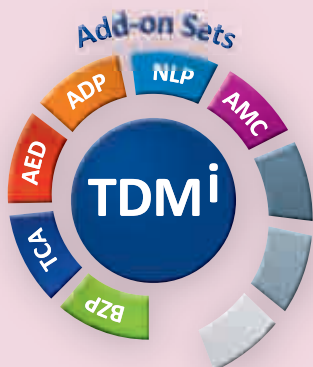
Antimycotics in Serum / Plasma

Invasive fungal infections, predominantly aspergillosis and candidiasis are the most important causes of morbidity and mortality in immunocompromised patients. Antimycotics are used for the treatment and prophylaxis of fungal infections. Antifungal drugs show large intra- and interindividual variabilities in pharmacokinetics, therefore the accurate measurement of the individual drug concentration in serum/plasma is essential for therapy control and success.

The ClinMass® Add-On Set for Antimycotics (order no. MS9650) contains all analyte specific components required for the determination of 7 drugs and metabolites.

The ClinMass® TDM Platform (order no. MS9050) contains the components needed for on-line SPE LCMS/MS analysis. It can be used with all ClinMass® Add-on Sets of the “TDM Kit System, on-line”. The analytical column is suitable for the whole analyte panel (147 compounds).

- No manual sample preparation needed
- Flexible and fast LC-MS/MS
Analysis: 3.5 min
- IS contains 7 isotope
labelled analytes



Test Data

Test data are available on request.

LC-MS/MS Parameters

LC-Parameters

Pump 1 (SPE): gradient program
(2.0 -4.0 ml/min)

Pump 2
(Mobile Phase A, B): gradient program
(0,05 ml/min)

Injection volume: 3-15 µl*

Injection interval: 3.5 min

Column heater: 40 °C

* depending on the sensitivity of the mass spectrometer

MS-Parameters

Ion source: ESI, positive/negative

MS/MS mode: MRM

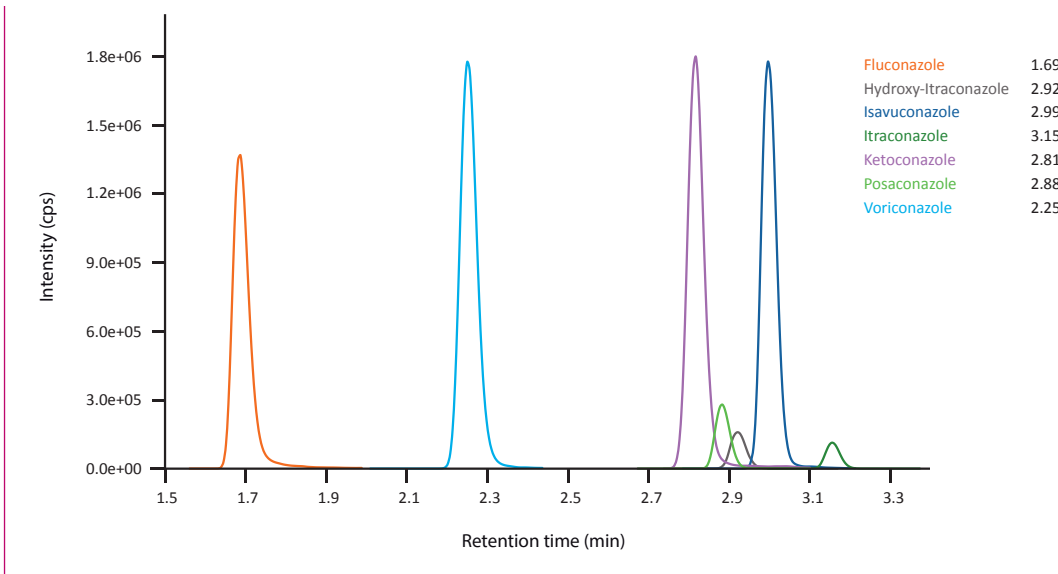
Sample Preparation

No manual sample preparation needed!

Direct injection of sample and Internal Standard IS
in the ratio 1:1 (autosampler).

Direct injection!

Chromatogram of the ClinCal® Serum Calibrator, Level 2 (order no. MS9613)



Ordering Information

| Order No. | Description | Quantity |
|-------------------------------------------|-----------------------------------------------------------------------------------------|---------------|
| MS9050 | ClinMass® TDM Platform, on-line for 400 assays | 1 pce. |
| Kit Components (order no. 9050): | | |
| MS9005 | Autosampler Washing Solution | 1 x 1000 ml |
| MS9007 | Mobile Phase A | 2 x 1000 ml |
| MS9008 | Mobile Phase B | 1 x 1000 ml |
| MS9059 | SPE-Buffer Load L | 2 x 2500 ml |
| MS9060 | SPE-Buffer Wash W | 2 x 2500 ml |
| MS9071 | Reconstitution Solution R | 1 x 5ml |
| Start Accessories: | | |
| MS9035 | Analytical Column with test chromatogram | 1 pce. |
| MS9031 | SPE-Column | 1 pce. |
| MS9032 | Prefilter | 1 pce. |
| Accessories: | | |
| MS9022 | Diluting Solution D | 50 ml |
| FK7400 | Inline-Filter (stainless steel sieve, free of dead volume) | 1 pce. |
| FK7340 | Sealings and sieves for order no. FK7400 | 4 pcs. each |
| MS9650 | ClinMass® Add-on Set, on-line, for Antimycotics in Serum / Plasma for 400 assays | 1 pce. |
| Kit Components (order no. MS9650): | | |
| MS9662 | Internal Standard IS, lyophil. | 5 ml |
| MS9613 | Serum Calibrator Set, lyophil. (Level 0 - 3) | 4 x 1 x 1 ml |
| | Manual | 1 pce |
| Separately available components: | | |
| MS9662 | Internal Standard IS, lyophil. | 5 ml |
| MS9613 | Serum Calibrator Set, lyophil. (Level 0 - 3) | 4 x 1 x 1 ml |
| Start Accessories: | | |
| MS9614 | Optimisation Mix, lyophil. | 2 ml |
| ClinChek® Controls: | | |
| MS9682 | Serum Control, lyophil., Level I, II | 2 x 5 x 1 ml |

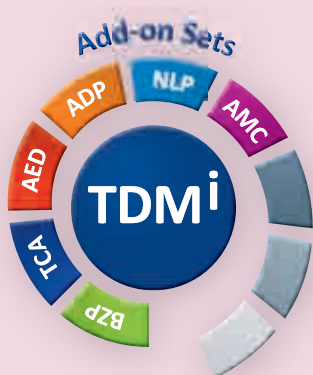
Benzodiazepines in Serum / Plasma

Benzodiazepines are a group of psychoactive drugs with a broad range of therapeutic effects and belong to the most frequently prescribed drugs all over the world.

The ClinMass® Add-on Set for Benzodiazepines (order no. MS9550) contains all analyte specific components required for the quantification of 35 different drugs and metabolites.

The ClinMass® TDM Platform (order no. MS9050) contains the components needed for on-line SPE LCMS/MS analysis. It can be used with all ClinMass® Add-on Sets of the “TDM Kit System, on-line”. The analytical column is suitable for the whole analyte panel (147 compounds).

- No manual sample preparation needed
- Flexible and fast LC-MS/MS Analysis (7.5 min)
- IS contains 20 isotope labeled analytes



Test Data

Test data are available on request.

LC-MS/MS Parameters

LC-Parameters

Pump 1 (SPE): gradient program
(0.1 - 4 ml/min)

Pump 2
(Mobile Phase A, B): gradient program
(0.6 ml/min)

Injection volume: 2 - 20 µl*

Injection interval: 7.5 min

Column heater: 40 °C

* depending on the sensitivity of the mass spectrometer

MS-Parameters

Ion source: ESI, positive

MS/MS mode: MRM

Sample Preparation

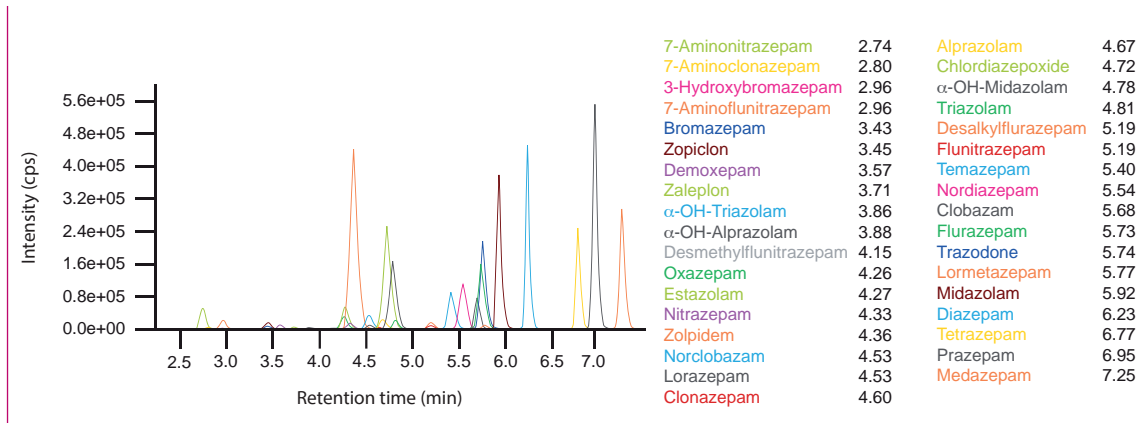
No manual sample preparation needed!

Direct injection of sample and Internal Standard IS in the ratio 1:1 (autosampler).

Direct injection!

3.2.3 TDM Kit System, on-line

Chromatogram of the ClinCal® Serum Calibrator, Level 2 (order no. MS6013)



Ordering Information

| Order No. | Description | Quantity |
|-------------------------------------------|--------------------------------------------------------------------------------------------|--------------------------|
| MS9050 | ClinMass® TDM Platform, on-line for 400 assays | 1 pce. |
| Kit Components (order no. MS9050): | | |
| MS9005 | Autosampler Washing Solution | 1000 ml |
| MS9007 | Mobile Phase A | 2 x MS9007 (2 x 1000 ml) |
| MS9008 | Mobile Phase B | 1000 ml |
| MS9059 | SPE-Buffer Load L | 2 x MS9059 (2 x 2500 ml) |
| MS9060 | SPE-Buffer Wash W | 2 x MS9060 (2 x 2500 ml) |
| MS9071 | Reconstitution Solution R | 5 ml |
| Start Accessories: | | |
| MS9035 | Analytical Column with test chromatogram | 1 pce. |
| MS9031 | SPE-Column | 1 pce. |
| MS9032 | Prefilter | 1 pce. |
| Accessories: | | |
| MS9022 | Diluting Solution D | 50 ml |
| FK7400 | Inline-Filter (stainless steel sieve, free of dead volume) | 1 pce. |
| FK7340 | Sealings and sieves for order no. FK7400 | 4 pcs. each |
| MS9550 | ClinMass® Add-on Set, on-line, for Benzodiazepines in Serum / Plasma for 400 assays | 1 pce. |
| Kit Components (order no. MS9550): | | |
| MS9562 | Internal Standard IS, lyophil. | 5 ml |
| MS6013 | Serum Calibrator Set, lyophil. (Level 0 - 3) | 4 x 1 x 1 ml |
| | Manual | 1 pce. |
| Start Accessories: | | |
| MS6015 - MS6019 | Optimisation Mix 1 - 5, lyophil. | 2 ml each |
| ClinChek® Controls: | | |
| MS6082 | Serum Control, lyophil., Level I, II | 2 x 5 x 1 ml |

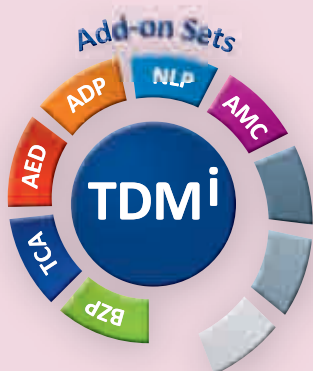
Neuroleptics in Serum / Plasma

Neuroleptics belong to the class of psychoactive drugs and are administered in the therapy of psychoses, in particular the symptomatic treatment of schizophrenia.

The ClinMass® Add-On Set, for Neuroleptics, on-line, (order no. MS9350) contains all analyte-specific components for the determination of 28 different neuroleptics. The analysis is performed by HPLC with tandem mass spectrometry (LC-MS/MS).

The ClinMass® TDM Platform contains the components needed for sample preparation and LC-MS/MS analysis.

- Flexible and fast on-line SPE Analysis (7.0 min)
- Comprehensive analyte spectrum
- IS contains 25 isotope labelled analytes



Test Data

Test data are available on request.

LC-MS/MS Parameters

LC-Parameters

| | |
|---------------------|--------------------------------------|
| Binary HPLC pump: | Mobile Phases A / B (0.65 ml/min) |
| Binary HPLC pump: | SPE-Buffer L / W (0.1 - 4 ml/min) |
| Injection volume: | 3 - 15 µl |
| Injection interval: | 7.0 min |
| Column heater: | 40 °C |

MS-Parameters

| | |
|-------------|-----|
| Ion source: | ESI |
| MS/MS mode: | MRM |

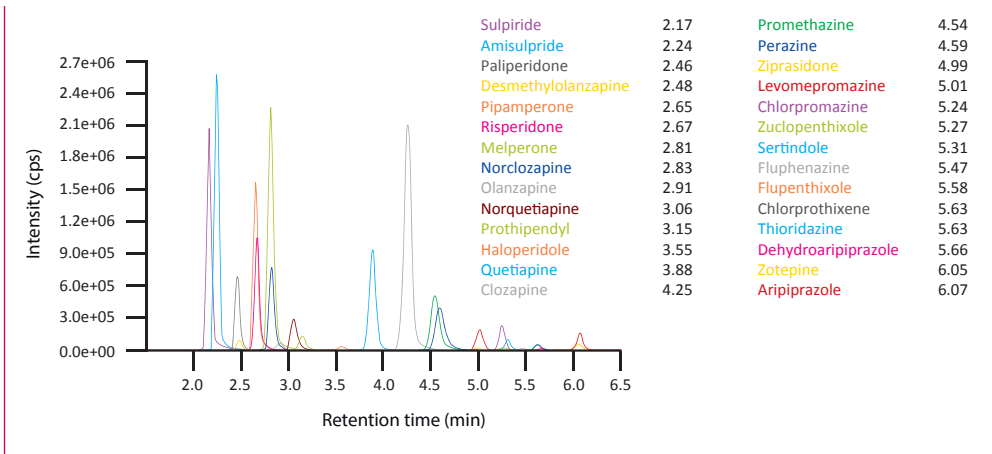
Sample Preparation

No manual sample preparation needed!

Direct injection of sample and Internal Standard IS in the ratio 1:2 (autosampler)

Direct injection!

Chromatogram of the ClinCal® Serum Calibrator, Level 2 (order no. MS9313)



Ordering Information

| Order No. | Description | Quantity |
|-------------------------------------------|-----------------------------------------------------------------------------------------|-------------------------|
| MS9050 | ClinMass® TDM Platform, on-line for 400 assays | 1 pce. |
| Kit Components (order no. MS9050): | | |
| MS9005 | Autosampler Washing Solution | 1000 ml |
| MS9007 | Mobile Phase A | 2 x MS9007 (2x 1000 ml) |
| MS9008 | Mobile Phase B | 1000 ml |
| MS9059 | SPE-Buffer Load L | 2500 ml |
| MS9060 | SPE-Buffer Wash W | 2500 ml |
| MS9071 | Reconstitution Solution R | 5 ml |
| Start Accessories: | | |
| MS9035 | Analytical Column with test chromatogram | 1 pce. |
| MS9031 | SPE-Column | 1 pce. |
| MS9032 | Prefilter | 1 pce. |
| Accessories: | | |
| MS9022 | Diluting Solution D | 50 ml |
| FK7400 | Inline-Filter (stainless steel sieve, free of dead volume) | 1 pce. |
| FK7340 | Sealings and sieves for order no. FK7400 | 4 pcs. each |
| MS9350 | ClinMass® Add-on Set, on-line, for Neuroleptics in Serum / Plasma for 400 assays | 1 pce. |
| Kit Components (order no. MS9350): | | |
| MS9362 | Internal Standard IS, lyophil. | 5 ml |
| MS9313 | Serum Calibrator Set, lyophil. (Level 0 - 3) | 4 x 1 x 1 ml |
| | Manual | |
| Start Accessories: | | |
| MS9314 | Optimisation Mix, lyophil. | 2 x 1 x 2 ml |
| ClinChek® Controls: | | |
| MS9382 | Serum Control, lyophil., Level I, II | 2 x 5 x 1 ml |

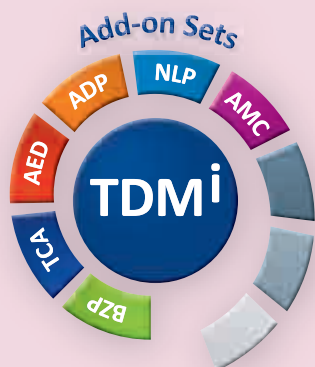
Tricyclic Antidepressants in Serum / Plasma

Tricyclic antidepressants (TCA) are a group of psychoactive drugs which are mainly used for the therapy of endogene depressions, anxiety and pain management.

The ClinMass® Add-on Set for TCAs (order no. MS9150) contains all analyte specific components required for the quantification of 13 TCAs and 2 atypical neuroleptics.

The ClinMass® TDM Platform (order no. MS9050) contains the components needed for on-line SPE LCMS/ MS analysis. It can be used with all ClinMass® Add-on Sets of the “TDM Kit System, on-line” (BZP, TCA, ...). The analytical column is suitable for the whole analyte panel (147 compounds).

- No manual sample preparation needed
- Flexible and fast LC-MS/MS Analysis (3.8 min)
- IS contains 12 isotope labeled analytes



Test Data

Test data are available on request.

LC-MS/MS Parameters

LC-Parameters

Pump 1 (SPE): gradient program
(0.1 - 5 ml/min)

Pump 2
(Mobile Phase A, B): gradient program
(0.8 ml/min)

Injection volume: 3 - 15 µl*

* depending on the sensitivity of the mass spectrometer

Injection interval: 3.8 min

Column heater: 40 °C

MS-Parameters

Ion source: ESI, positive

MS/MS mode: MRM

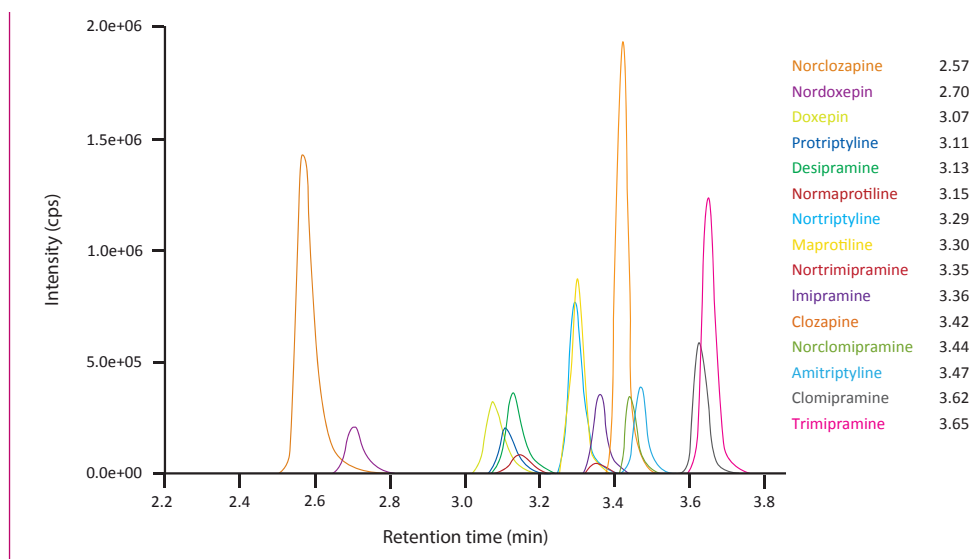
Sample Preparation

No manual sample preparation needed!

Direct injection of sample and Internal Standard IS in the ratio 1:2 (autosampler).

Direct injection!

Chromatogram of the ClinCal® Serum Calibrator, Level 2 (order no. MS9113)



Ordering Information

| Order No. | Description | Quantity |
|-------------------------------------------|------------------------------------------------------------------------------------------------------|--------------------------|
| MS9050 | ClinMass® TDM Platform, on-line for 400 assays | 1 pce. |
| Kit Components (order no. MS9050): | | |
| MS9005 | Autosampler Washing Solution | 1000 ml |
| MS9007 | Mobile Phase A | 2 x MS9007 (2 x 1000 ml) |
| MS9008 | Mobile Phase B | 1000 ml |
| MS9059 | SPE-Buffer Load L | 2 x MS9059 (2 x 2500 ml) |
| MS9060 | SPE-Buffer Wash W | 2 x MS9060 (2 x 2500 ml) |
| MS9071 | Reconstitution Solution R | 5 ml |
| Start Accessories: | | |
| MS9035 | Analytical Column with test chromatogram | 1 pce. |
| MS9031 | SPE-Column | 1 pce. |
| MS9032 | Prefilter | 1 pce. |
| Accessories: | | |
| MS9022 | Diluting Solution D | 50 ml |
| FK7400 | Inline-Filter (stainless steel sieve, free of dead volume) | 1 pce. |
| FK7340 | Sealings and sieves for order no. FK7400 | 4 pcs. each |
| MS9150 | ClinMass® Add-on Set, on-line, for Tricyclic Antidepressants in Serum / Plasma for 400 assays | 1 pce. |
| Kit Components (order no. MS9150): | | |
| MS9162 | Internal Standard IS, lyophil. | 5 ml |
| MS9113 | Serum Calibrator Set, lyophil. (Level 0 - 3) | 4 x 1 x 1 ml |
| | Manual | 1 pce. |
| Start Accessories: | | |
| MS9114 | Optimisation Mix, lyophil. | 3 x 1 x 2 ml |
| ClinChek® Controls: | | |
| MS9182 | Serum Control, lyophil., Level I, II | 2 x 5 x 1 ml |

3.3.1 Newborn Screening (NBS)

Amino Acids and Acylcarnitines in Dried Blood Spots (DBS)

The determination of the amino acids and acylcarnitines profile is an integral part of national newborn screening programmes. For this purpose RECIPE offers an approved ClinSpot® LC-MS/MS Complete Kit for the use in accredited screening laboratories (order no. MS10000). The kit contains all reagents needed for the analysis of 26 analytes. The determination of additional acylcarnitines is possible. The entire sample preparation is performed with 96-well plates, in order to ensure a high sample throughput.

- Method according to CLSI NBS-04

Test Data

Test data are available on request.

LC-MS/MS Parameters

LC-Parameters

Pump: isocratic (0.1 ml/min)
Injection volume: 5 - 20 µl
Injection interval: 1.0 - 1.5 min

MS-Parameters

Ion source: ESI, positive
MS/MS mode: MRM

Sample Preparation

Extraction:

| | |
|---------------------------|-----------------------------|
| well-plate 1: 3.2 mm disc | 100 µl Internal Standard IS |
|---------------------------|-----------------------------|

extract



Transfer:

Transfer supernatant into well-plate 2

evaporate



Derivatisation:

Add 50 µl Reagent B

1. incubate (60 °C)
2. evaporate



Reconstitution:

Add 100 µl Reagent C

reconstitute



LC-MS/MS Analysis:

Inject 10 - 20 µl



3.3.1 Newborn Screening (NBS)

| Amino acids | Acylcarnitines | Additional acylcarnitines | |
|---------------|----------------|---------------------------|-------------------|
| Alanine | Carnitine | C3DC-Carnitine | C16:1-Carnitine |
| Arginine | C2-Carnitine | C4OH-Carnitine | C16:1OH-Carnitine |
| Aspartic acid | C3-Carnitine | C4DC-Carnitine | C16OH-Carnitine |
| Citrulline | C4-Carnitine | C5:1-Carnitine | C18:2-Carnitine |
| Glutamic acid | C5-Carnitine | C5OH-Carnitine | C18:1-Carnitine |
| Glycine | C5DC-Carnitine | C6DC-Carnitine | C18:2OH-Carnitine |
| Leucine | C6-Carnitine | C8:1-Carnitine | C18:1OH-Carnitine |
| Methionine | C8-Carnitine | C10:2-Carnitine | C18OH-Carnitine |
| Ornithine | C10-Carnitine | C10:1-Carnitine | |
| Phenylalanine | C12-Carnitine | C12:1-Carnitine | |
| Proline | C14-Carnitine | C14:2-Carnitine | |
| Tyrosine | C16-Carnitine | C14:1-Carnitine | |
| Valine | C18-Carnitine | C14OH-Carnitine | |

Ordering Information

| Order No. | Description | Quantity |
|--------------------------------------------|------------------------------------------------------------------------------------------------------------|---------------------------|
| MS10000 | ClinSpot® Complete Kit for Amino Acids and Acylcarnitines in Dried Blood Spots (DBS) for 960 assays | 1 pce. |
| Kit Components (order no. MS10000): | | |
| MS10005 | Autosampler Washing Solution | 1000 ml |
| MS10010 | Mobile Phase | 1000 ml |
| MS10012A | Internal Standard IS, lyophil. | 100 ml |
| MS10021 | Reagent A | 100 ml |
| MS10022 | Reagent B | 50 ml |
| MS10023 | Reagent C | 100 ml |
| MS10040 | 96-Well Plates (370 µl) | 6 x MS10040 (6 x 5 pcs.) |
| MS10041 | Covers for 96-Well Plates | 2 x MS10041 (2 x 15 pcs.) |
| MS10182 | Dried Blood Spot Control, Level I, II | 2 x 1 x 3 spots |
| | Manual | 1 pce. |
| Additional Components: | | |
| MS10012 | Internal Standard IS, lyophil. | 25 ml |
| MS10014 | Optimisation Mix | 2 x 1 x 5 ml |
| Accessories: | | |
| MS10042 | Protective sheets for 96-well-plate (PE/PP foil, 80 x 140 mm) | 50 pcs. |
| MS10045 | Backpressure regulator, PEEK version, 34 bar | 1 pce. |
| MS10046 | Replacement cartridge gold coat, 34 bar | 1 pce. |
| FK7400 | Inline-Filter (stainless steel sieve, free of dead volume) | 1 pce. |
| FK7340 | Sealings and Sieves for order no. FK7400 | 4 pcs. each |
| ClinChek® Controls: | | |
| MS10182 | Dried Blood Spot Control, Level I, II | 2 x 1 x 3 spots |

Amino Acids and Acylcarnitines in Dried Blood Spots (DBS) with Filter-Plates

The determination of the amino acids and acylcarnitines profile is an integral part of national newborn screening programmes. For this purpose RECIPE offers an approved ClinSpot® LC-MS/MS Complete Kit for the use in accredited screening laboratories (order no. MS10100). The kit contains all reagents needed for the analysis of 26 analytes. The determination of additional acylcarnitines is possible. With this kit (MS10100) the sample preparation is performed with 96-well plates combined with filter-plates.

- Method according to CLSI NBS-04
- Timesaving in sample preparation



Test Data

Test data are available on request.

LC-MS/MS Parameters

LC-Parameters

Pump: isocratic (0.1 ml/min)
Injection volume: 5 - 20 µl
Injection interval: 1.0 - 1.5 min

MS-Parameters

Ion source: ESI, positive
MS/MS mode: MRM

Sample Preparation

Extraction:

| | |
|--------------------------------------------------|--------------------------------|
| <i>filter-plate + well-plate:</i> 3.2 mm disc | 100 µl Internal Standard IS |
|--------------------------------------------------|--------------------------------|

1. extract
2. centrifuge
3. evaporate filtrate

Derivatisation:

Add 50 µl Reagent B

1. incubate (60 °C)
2. evaporate

Reconstitution:

Add 100 µl Reagent C

reconstitute

LC-MS/MS Analysis:

Inject 10 - 20 µl

3.3.1 Newborn Screening (NBS)

| Amino acids | Acylcarnitines | Additional acylcarnitines | |
|---------------|----------------|---------------------------|-------------------|
| Alanine | Carnitine | C3DC-Carnitine | C16:1-Carnitine |
| Arginine | C2-Carnitine | C4OH-Carnitine | C16:1OH-Carnitine |
| Aspartic acid | C3-Carnitine | C4DC-Carnitine | C16OH-Carnitine |
| Citrulline | C4-Carnitine | C5:1-Carnitine | C18:2-Carnitine |
| Glutamic acid | C5-Carnitine | C5OH-Carnitine | C18:1-Carnitine |
| Glycine | C5DC-Carnitine | C6DC-Carnitine | C18:2OH-Carnitine |
| Leucine | C6-Carnitine | C8:1-Carnitine | C18:1OH-Carnitine |
| Methionine | C8-Carnitine | C10:2-Carnitine | C18OH-Carnitine |
| Ornithine | C10-Carnitine | C10:1-Carnitine | |
| Phenylalanine | C12-Carnitine | C12:1-Carnitine | |
| Proline | C14-Carnitine | C14:2-Carnitine | |
| Tyrosine | C16-Carnitine | C14:1-Carnitine | |
| Valine | C18-Carnitine | C14OH-Carnitine | |

Ordering Information

| Order No. | Description | Quantity |
|--------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------|--------------------------|
| MS10100 | ClinSpot® Complete Kit for Amino Acids and Acylcarnitines in Dried Blood Spots (DBS) with Filter-Plates, for 960 assays | 1 pce. |
| Kit Components (order no. MS10100): | | |
| MS10005 | Autosampler Washing Solution | 1000 ml |
| MS10010 | Mobile Phase | 1000 ml |
| MS10012A | Internal Standard IS, lyophil. | 100 ml |
| MS10021 | Reagent A | 100 ml |
| MS10022 | Reagent B | 50 ml |
| MS10023 | Reagent C | 100 ml |
| MS10040 | 96-Well Plates (370 µl) | 3 x MS10040 (3 x 5 pcs.) |
| MS10041 | Covers for 96-Well Plates | 15 pcs. |
| MS10140 | 96-Well Filter Plates (500 µl) with Covers | 3 x MS10140 (3 x 5 pcs.) |
| MS10182 | Dried Blood Spot Control, Level I, II | 2 x 1 x 3 spots |
| | Manual | 1 pce. |
| Additional Components: | | |
| MS10012 | Internal Standard IS, lyophil. | 25 ml |
| MS10014 | Optimisation Mix | 2 x 1 x 5 ml |
| Accessories: | | |
| MS10042 | Protective sheets for 96-well-plate (PE/PP foil, 80 x 140 mm) | 50 pcs. |
| MS10045 | Backpressure regulator, PEEK version, 34 bar | 1 pce. |
| MS10046 | Replacement cartridge gold coat, 34 bar | 1 pce. |
| FK7400 | Inline-Filter (stainless steel sieve, free of dead volume) | 1 pce. |
| FK7340 | Sealings and Sieves for order no. FK7400 | 4 pcs. each |
| ClinChek® Controls: | | |
| MS10182 | Dried Blood Spot Control, Level I, II | 2 x 1 x 3 spots |

3.3.1 Newborn Screening (NBS)

Homocysteine in Dried Blood Spots (DBS)

The determination of homocysteine in dried blood spots (DBS) is used for the newborn screening for inherited defects of the methionine metabolism (homocystinuria). The RECIPE ClinSpot® Complete Kit allows a reliable determination of total homocysteine from DBS. After sample preparation (reduction and precipitation step) the sample analysis is performed with an injection interval of 1.0 min only. Optionally the sample preparation can be performed in 96-well plates.

- Injection interval: 1.0 min

Test Data

| | |
|-----------------------|-----------------------------|
| Linearity: | 0.2 - 104 $\mu\text{mol/l}$ |
| LOD: | 0.07 $\mu\text{mol/l}$ |
| LLOQ: | 0.2 $\mu\text{mol/l}$ |
| Intraassay precision: | 2.8 % |
| Interassay precision: | 3.8 % |

LC-MS/MS Parameters

LC-Parameters

| | |
|---------------------|------------------------|
| Pump: | isocratic (0.7 ml/min) |
| Injection volume: | 1 μl |
| Injection interval: | 1.0 min |
| Column heater: | room temperature |

MS-Parameters

| | |
|-------------|---------------|
| Ion source: | ESI, positive |
| MS/MS-Mode: | MRM |

Sample Preparation

Reduction:

| | |
|--------------------------------------------------------------|----------------------------|
| Filter Spot Sample (+ 15 μl Internal Standard) | 15 μl Reagent A |
|--------------------------------------------------------------|----------------------------|

mix

Precipitation

| |
|-----------------------------|
| 100 μl Reagent B |
|-----------------------------|

1. mix
2. centrifuge

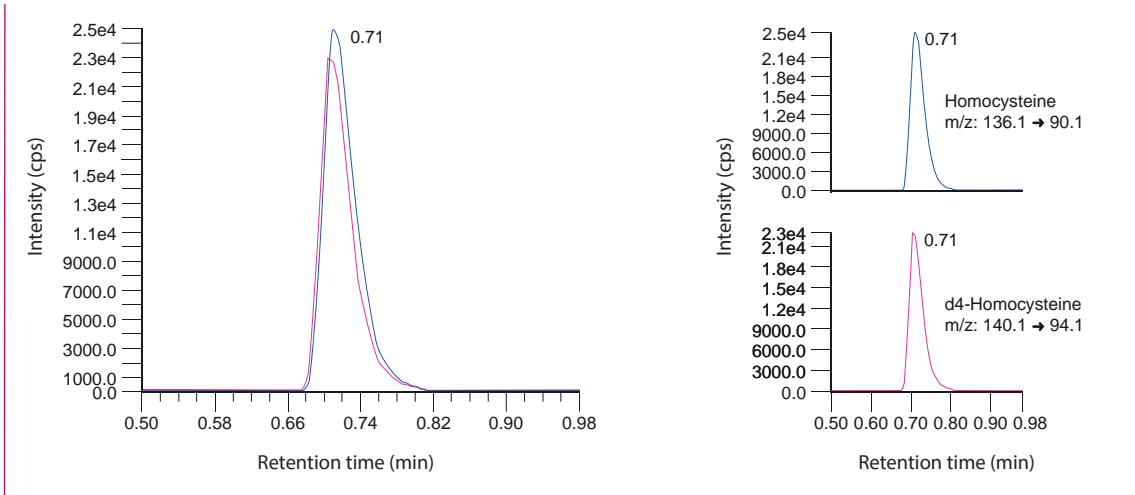
LC-MS/MS Analysis:

| |
|-------------------------------------------|
| Inject 1 μl of the supernatant |
|-------------------------------------------|



3.3.1 Newborn Screening (NBS)

Chromatogram (left) and mass traces (right) of the ClinCal® Dried Blood Spot Calibrator, Level 3 (order no. MS2113)



Ordering Information

| Order No. | Description | Quantity |
|-------------------------------------------|------------------------------------------------------------------------------------------|---------------------------|
| MS2100 | ClinSpot® Complete Kit for Homocysteine in Dried Blood Spots (DBS) for 300 assays | 1 pce. |
| Kit Components (order no. MS2100): | | |
| MS2005 | Autosampler Washing Solution | 1000 ml |
| MS2010 | Mobile Phase | 800 ml |
| MS2112 | Internal Standard IS, lyophil. | 5 ml |
| MS2113 | Dried Blood Spot Calibrator Set (Level 0 - 3) | 4 x 1 x 3 spots |
| MS2020 | Sample Preparation Vials | 3 x MS2020 (3 x 100 pcs.) |
| MS2021 | Reagent A | 5 ml |
| MS2022 | Reagent B | 30 ml |
| | Manual | 1 pce. |
| Start Accessories: | | |
| MS2030 | Analytical Column with test chromatogram | 1 pce. |
| Accessories: | | |
| FK6501 | Protective Sheets for 96-Well Plates (PE/PP foil, 80 x 140 mm) | 50 pcs. |
| FK6510 | 96-Well Plates (370 µl) | 5 pcs. |
| ClinChek® Controls: | | |
| MS2182 | Dried Blood Spot Control, Level I, II | 2 x 1 x 3 spots |



4. LC-MS/MS Opti Mix and IS

4.1 ClinMass® Optimisation Mixes.....160

4.2 ClinMass® Internal Standards164

ClinMass® Optimisation Mixes are intended for the optimisation of the MS/MS parameters and for the subsequent check-up of the analytical system. ClinMass® Internal Standards are used for the internal standardisation of the LC-MS/MS analysis.

ClinMass® Optimisation Mixes and ClinMass® Internal Standards are primarily intended to be used with LC-MS/MS Complete Kits of RECIPE (CE-IVD). In addition they may be used as kit-independent IVD reagents for the implementation or verification of inhouse methods.



Product Overview

► Amino Acids and Acylcarnitines

Analytes:

Optimisation Mix Amino Acids

¹³C₃¹⁵N-Alanine, ¹³C₆-Arginine, ¹³C₄-Aspartic Acid, ²H₃-Citrulline, ¹³C₅-Glutamic Acid, ²⁻¹³C¹⁵N-Glycine, ²H₃-Leucine, ²H₃-Methionine, ²H₆-Ornithine, ¹³C₆-Phenylalanine, ¹³C₅-Proline, ¹³C₆-Tyrosine, ²H₆-Valine

Optimisation Mix Acylcarnitines

²H₆-Carnitine (²H₉-C0),
²H₃-Acetylcarnitine (²H₃-C2),
²H₃-Propionylcarnitine (²H₃-C3),
²H₃-Butyrylcarnitine (²H₃-C4),
²H₆-Isovalerylcarnitine (²H₉-C5),
²H₆-Glutaryl carnitine (²H₉-C5DC),
²H₃-Hexanoylcarnitine (²H₃-C6),
²H₃-Octanoylcarnitine (²H₃-C8),
²H₃-Decanoylcarnitine (²H₃-C10),
²H₃-Dodecanoylcarnitine (²H₃-C12),
²H₃-Tetradecanoylcarnitine (²H₃-C14),
²H₃-Hexadecanoylcarnitine (²H₃-C16),
²H₃-Octadecanoylcarnitine (²H₃-C18)

| Order No. | Description | Quantity |
|-----------|------------------------------------------------------------------------------------------------------------------|--------------|
| MS10014 | ClinMass® Optimisation Mix for Amino Acids and Acylcarnitines, lyophil. for kit order number MS10000 and MS10100 | 2 x 1 x 5 ml |

► Antidepressants

Analytes:

Optimisation Mix 1:

Atomoxetine, Bupropion, Citalopram, Desmethylmianserin, Dosulepin, Fluoxetine, Methylphenidate, Mianserin, Milnacipran, Mirtazapine, Opipramol, Reboxetine, Sertraline, Tianeptine, Tramadol, Trazodone, Venlafaxine, Vortioxetine

Optimisation Mix 2:

Agomelatine, Clomethiazole, Desmethylcitalopram, Desmethylfluoxetine, Desmethylmirtazapine, Desmethylsertraline, erythro-Dihydro-Bupropion, Duloxetine, Fluvoxamine, Guanfacine, Hydroxybupropion, Moclobemide, Nefazodone, O-Desmethyltramadol, O-Desmethylvenlafaxine, Paroxetine, Ritalinic Acid, Tranlycypromine

| Order No. | Description | Quantity |
|-----------|--------------------------------------------------------------------------------------|--------------|
| MS9414 | ClinMass® Optimisation Mix, for Antidepressants, lyophil. (Optimisation Mix 1 and 2) | 2 x 1 x 2 ml |

Product Overview

| Order No. | Description | Quantity |
|-----------|-----------------------------------------------------------------------------------------------------------|--------------|
| MS9114 | ClinMass® Optimisation Mix for Tricyclic Antidepressants, lyophil. (consisting of Optimisation Mix 1 - 3) | 3 x 1 x 2 ml |

Antidepressants, tricyclic

► Analytes:

Optimisation Mix 1:

Amitriptyline, Clozapine, Imipramine, Nordoxepin, Nortriptyline

Optimisation Mix 2:

Maprotiline, Norclomipramine, Norclozapine, Nortrimipramine, Protriptyline

Optimisation Mix 3:

Clomipramine, Desipramine, Doxepin, Normaprotiline, Trimipramine

| Order No. | Description | Quantity |
|-----------|-----------------------------------------------------------------------------------------------------|--------------|
| MS9214 | ClinMass® Optimisation Mix for Antiepileptic Drugs, lyophil. (consisting of Optimisation Mix 1 - 5) | 5 x 1 x 2 ml |

► Antiepileptic Drugs

Analytes:

Optimisation Mix 1:

Brivaracetam, Carbamazepine, Felbamate, Oxcarbazepine, PEMA, Rufinamide, Vigabatrine

Optimisation Mix 2:

10-OH-Carbamazepine, Gabapentine, Perampanel, Phenytoin, Rufinamid, Stiripentol

Optimisation Mix 3:

Carbamazepine-Diol, Lacosamide, Levetiracetam, Pregabalin, Theophylline

Optimisation Mix 4:

Carbamazepine-Epoxyde, Lamotrigine, Primidone, Retigabine, Tiagabine

Optimisation Mix 5:

Ethosuximide, NDMS, Phenobarbital, Sulthiame, Topiramate, Valproic Acid, Zonisamide

| Order No. | Description | Quantity |
|-----------|-------------------------------------------------------|----------|
| MS9614 | ClinMass® Optimisation Mix for Antimycotics, lyophil. | 2 ml |

► Antimycotics

Analytes:

Optimisation Mix:

5-Fluorocytosine, Amphotericin B, Anidulafungin, Fluconazole, Isavuconazole, Itraconazole, Ketoconazole, Micafungin, OH-Itraconazole, Posaconazole, Voriconazole, Voriconazol N-Oxide

4.1 ClinMass® Optimisation Mixes

► Benzodiazepines

Analytes:

Optimisation Mix 1:

7-Aminoflunitrazepam, 7-Aminonitrazepam, Demoxepam, Flunitrazepam, 3-Hydroxybromazepam, Prazepam, Temazepam

Optimisation Mix 2:

Bromazepam, Clobazam, Lormetazepam, Nitrazepam, Norclobazam, Nordiazepam, Zopiclone + ACP

Optimisation Mix 3:

7-Aminoclonazepam, alpha-Hydroxymidazolam, Alprazolam, Clonazepam, Desmethylflunitrazepam, Medazepam, Midazolam, Tetrazepam

Optimisation Mix 4:

alpha-Hydroxyalprazolam, Chlordiazepoxide, Desalkylflurazepam, Diazepam, Flurazepam, Trazodone, Zolpidem

Optimisation Mix 5:

alpha-Hydroxytriazolam, Brotizolam, Estazolam, Lorazepam, Oxazepam, Triazolam, Zaleplon

| Order No. | Description | Quantity |
|-----------|-------------------------------------------------------------|----------|
| MS6015 | ClinMass® Optimisation Mix 1, lyophil., for Benzodiazepines | 2 ml |

| Order No. | Description | Quantity |
|-----------|-------------------------------------------------------------|----------|
| MS6016 | ClinMass® Optimisation Mix 2, lyophil., for Benzodiazepines | 2 ml |

| Order No. | Description | Quantity |
|-----------|-------------------------------------------------------------|----------|
| MS6017 | ClinMass® Optimisation Mix 3, lyophil., for Benzodiazepines | 2 ml |

| Order No. | Description | Quantity |
|-----------|-------------------------------------------------------------|----------|
| MS6018 | ClinMass® Optimisation Mix 4, lyophil., for Benzodiazepines | 2 ml |

| Order No. | Description | Quantity |
|-----------|-------------------------------------------------------------|----------|
| MS6019 | ClinMass® Optimisation Mix 5, lyophil., for Benzodiazepines | 2 ml |

► Ethylglucuronide and Ethylsulfate

Analytes:

Optimisation Mix:

Ethylglucuronide, d5-Ethylglucuronide, Ethylsulfate, d5-Ethylsulfate

| Order No. | Description | Quantity |
|-----------|------------------------------------------------------------------|----------|
| MS8014 | ClinMass® Optimisation Mix for Ethylglucuronide and Ethylsulfate | 2 ml |

► Immunosuppressants

Analytes:

Optimisation Mix1:

Cyclosporine A, Tacrolimus, Sirolimus, Everolimus

Optimisation Mix1:

d12-Cyclosporine A, 13Cd2-Tacrolimus, 13Cd3-Sirolimus, 13Cd4-Everolimus

| Order No. | Description | Quantity |
|-----------|----------------------------------------------------------------------------------------------------------|----------|
| MS1014 | ClinMass® Optimisation Mix 1, lyophil., for Immunosuppressants for kit order nos. MS1100, MS1200, MS1300 | 2 ml |

| Order No. | Description | Quantity |
|-----------|----------------------------------------------------------------------------------------------------------|----------|
| MS1115 | ClinMass® Optimisation Mix 2, lyophil., for Immunosuppressants for kit order nos. MS1100, MS1200, MS1300 | 2 ml |

► Metanephrines

Analytes:

Optimisation Mix:

3-Methoxytyramine, d4-3-Methoxytyramine, Metanephrine, d3-Metanephrine, Normetanephrine, d3-Normetanephrine

| Order No. | Description | Quantity |
|-----------|----------------------------------------------|----------|
| MS11014 | ClinMass® Optimisation Mix for Metanephrines | 2 ml |

4.1 ClinMass® Optimisation Mixes

| Order No. | Description | Quantity |
|-----------|----------------------------------------------|----------|
| MS5114 | ClinMass® Optimisation Mix for Methylmalonic | 2 ml |

► Methylmalonic Acid

Analytes:

Optimisation Mix:

Methylmalonic Acid, d3-Methylmalonic Acid

| Order No. | Description | Quantity |
|-----------|------------------------------------------------------------|----------|
| MS99114 | ClinMass® Optimisation Mix for Mycophenolic Acid, lyophil. | 2 ml |

► Mycophenolic Acid

Analytes:

Optimisation Mix:

Mycophenolic Acid

| Order No. | Description | Quantity |
|-----------|----------------------------------------------------------------------------------------------|--------------|
| MS9314 | ClinMass® Optimisation Mix for Neuroleptics, lyophil. (consisting of Optimisation Mix 1 + 2) | 2 x 1 x 2 ml |

► Neuroleptics

Analytes:

Optimisation Mix 1:

Amisulpride, Aripiprazole, Clozapine, Fluphenazine, Haloperidol, Melperone, Olanzapine, Perazine, Promethazine, Quetiapine, Risperidone, Sertindole, Sulpiride, Ziprasidone

Optimisation Mix 2:

Chlorpromazine, Chlorprothixene, Dehydro-Aripiprazole, Desmethylolanzapine, Flupenthixol, Levomepromazine, Norclozapine, Norquetiapine, Paliperidone, Pipamperone, Prothipendyl, Thioridazine, Zotepine, Zuclopenthixol)

| Order No. | Description | Quantity |
|-----------|-------------------------------------------|----------|
| MS12015 | ClinMass® Optimisation Mix 1 for Steroids | 2 ml |
| MS12016 | ClinMass® Optimisation Mix 2 for Steroids | 2 ml |

► Steroids

Analytes:

Optimisation Mix 1:

Androstenedione, 11-Deoxycortisol, 17-Hydroxyprogesterone, DHEAS

Optimisation Mix 2:

Cortisol, 21-Deoxycortisol, 21-Hydroxyprogesterone, Testosterone

| Order No. | Description | Quantity |
|-----------|----------------------------------------------------------------------------------------------|----------|
| MS7014 | ClinMass® Optimisation Mix for 25-OH-Vitamin D2/D3 for kit order nos. MS7000, MS7100, MS7200 | 2 ml |

► 25-OH Vitamin D2 / D3

Analytes:

Optimisation Mix for 25-OH-Vitamin D2/D3:

25-OH-Vitamin D3, 25-OH-Vitamin D2, d6-25-OH-Vitamin D3

Optimisation Mix for 25-OH-Vitamin D3 and 3-Epimer:

25-OH-Vitamin D3, 3-epi-25-OH-Vitamin D3

| Order No. | Description | Quantity |
|-----------|--------------------------------------------------------------------------------------------------------|----------|
| MS7015 | ClinMass® Optimisation Mix for 25-OH-Vitamin D3 and 3-Epimer for kit order nos. MS7000, MS7100, MS7200 | 1 ml |

Product Overview

► Amino Acids and Acylcarnitines

Analytes:

Amino Acids

¹³C₃¹⁵N-Alanine, ¹³C₆-Arginine, ¹³C₄-Aspartic Acid,
²H₃-Citrulline, ¹³C₅-Glutamic Acid,
²⁻¹³C¹⁵N-Glycine, ²H₃-Leucine, ²H₃-Methionine,
²H₆-Ornithine, ¹³C₆-Phenylalanine, ¹³C₅-Proline,
¹³C₆-Tyrosine, ²H₈-Valine

Acylcarnitines

²H₆-Carnitine (²H₅-C0), ²H₃-Acetylcarnitine
(²H₃-C2), ²H₃-Propionylcarnitine (²H₃-C3),
²H₃-Butyrylcarnitine (²H₃-C4),
²H₅-Isovalerylcarnitine (²H₅-C5),
²H₆-Glutarylacetyl (²H₆-C5DC),
²H₃-Hexanoylcarnitine (²H₃-C6),
²H₃-Octanoylcarnitine (²H₃-C8),
²H₃-Decanoylcarnitine (²H₃-C10),
²H₃-Dodecanoylcarnitine (²H₃-C12),
²H₃-Tetradecanoylcarnitine (²H₃-C14),
²H₃-Hexadecanoylcarnitine (²H₃-C16),
²H₃-Octadecanoylcarnitine (²H₃-C18)

| Order No. | Description | Quantity |
|-----------|-----------------------------------------------------------------------------------------------------------------|----------|
| MS10012 | ClinMass® Internal Standard, lyophil., for Amino Acids and Acylcarnitines for kit order no. MS10000 and MS10100 | 25 ml |
| MS10012A | ClinMass® Internal Standard, lyophil., for Amino Acids and Acylcarnitines for kit order no. MS10000 and MS10100 | 100 ml |

► Antidepressants

Analytes:

d₃-Agomelatine, d₅-Atomoxetine,
d₉-Bupropion, d₆-Citalopram,
d₃-Desmethylcitalopram,
d₅-Desmethylfluoxetine,
d₄-Desmethylsertraline,
d₆-O-Desmethyltramadol,
d₉-threo-Dihydro-Bupropion, d₃-Dosulepin,
d₇-Duloxetine, d₅-Fluoxetine, d₃-Fluvoxamine,
d₆-Hydroxybupropion, d₉-Methylphenidate,
d₃-Mianserin, d₁₀-Milnacipran, d₃-Mirtazapine,
d₈-Moclobemide, d₆-Nefazodone,
d₄-Opi Pramol, d₄-Paroxetine, d₅-Reboxetine,
d₃-Sertraline, d₆-Tramadol, d₅-Tranlycypromine,
d₆-Venlafaxine, d₈-Vortioxetine

| Order No. | Description | Quantity |
|-----------|-------------------------------------------------------------------------------------------------------------------|----------|
| MS9412 | ClinMass® Internal Standard, lyophil., for Antidepressants for TDM Platform, Add-on Set-order no. MS9400 | 5 x 5 ml |
| MS9462 | ClinMass® Internal Standard, lyophil., for Antidepressants for TDM Platform, on-line, Add-on Set order no. MS9450 | 5 ml |

Product Overview

| Order No. | Description | Quantity |
|-----------|-----------------------------------------------------------------------------------------------------------------------------|----------|
| MS9112 | ClinMass® Internal Standard, lyophil., for Tricyclic Antidepressants for TDM Platform, Add-on Set order no. MS9100 | 5 x 5 ml |
| MS9162 | ClinMass® Internal Standard, lyophil., for Tricyclic Antidepressants for TDM Platform, on-line, Add-on Set order no. MS9150 | 5 ml |

| Order No. | Description | Quantity |
|-----------|-----------------------------------------------------------------------------------------------------------------------|----------|
| MS9212 | ClinMass® Internal Standard, lyophil., for Antiepileptic Drugs for TDM Platform, Add-on Set-order no. MS9200 | 5 x 5 ml |
| MS9262 | ClinMass® Internal Standard, lyophil., for Antiepileptic Drugs for TDM Platform, on-line, Add-on Set order no. MS9250 | 5 ml |

| Order No. | Description | Quantity |
|-----------|----------------------------------------------------------------------------------------------------------------|----------|
| MS9612 | ClinMass® Internal Standard, lyophil., for Antimycotics for TDM Platform, Add-on Set-order no. MS9600 | 5 x 5 ml |
| MS9662 | ClinMass® Internal Standard, lyophil., for Antimycotics for TDM Platform, on-line, Add-on Set order no. MS9650 | 5 ml |

| Order No. | Description | Quantity |
|-----------|-------------------------------------------------------------------------------------------------------------------|----------|
| MS9512 | ClinMass® Internal Standard, lyophil., for Benzodiazepines for TDM Platform, Add-on Set-order no. MS9500 | 5 x 5 ml |
| MS9562 | ClinMass® Internal Standard, lyophil., for Benzodiazepines for TDM Platform, on-line, Add-on Set order no. MS9550 | 5 ml |

▶ Antidepressants, tricyclic

Analytes:

Optimisation Mix 1:

d₃-Amitriptyline, d₃-Clomipramine, d₄-Clozapine, d₃-Desipramine, d₃-Doxepin, d₃-Imipramine, d₅-Maprotiline, d₃-Norclomipramine, d₈-Norclozapine, d₃-Nordoxepin, d₃-Nortriptyline, d₃-Trimipramine

▶ Antiepileptic Drugs

Analytes:

d₇-Brivaracetam, d₁₀-Carbamazepine, d₄-10-OH-Carbamazepine, d₃-Ethosuximide, d₄-Felbamate, d₄-Gabapentine, d₃-Lacosamide, ¹³C₃-Lamotrigine, d₆-Levetiracetam, d₄-Oxcarbazepine, d₅-Phenobarbital, d₅-Perampanel, d₅-Phenylethylmalonamide (PEMA), d₁₀-Phenytoin, d₄-Pregabalin, d₅-Primidone, d₄-Retigabine, ¹⁵N,d₂-Rufinamide, d₉-Stiripentol, d₄-Sulthiame, d₆-Theophylline, d₆-Tiagabine, d₁₂-Topiramate, d₆-Valproic Acid, ¹⁵N,d₄-Zonisamide

▶ Antimycotics

Analytes:

¹³C¹⁵N₂-5-Fluorocytosine, d₄-Fluconazole, ¹³Cd₄-Isavuconazole, d₅-Itraconazole, d₈-Ketoconazole, d₅-OH-Itraconazole, d₄-Posaconazole, d₃-Voriconazole

▶ Benzodiazepines

Analytes:

d₄-7-Aminoclonazepam, d₇-7-Aminoflunitrazepam, d₅-a-Hydroxalprazolam, d₄-a-Hydroxymidazolam, d₄-a-Hydroxytriazolam, d₅-Alprazolam, d₅-Chlordiazepoxide, d₄-Clonazepam, d₅-Diazepam, d₅-Estazolam, d₇-Flunitrazepam, d₄-Lorazepam, d₄-Midazolam, d₅-Nitrazepam, d₅-Nordiazepam, d₅-Oxazepam, d₅-Prazepam, d₅-Temazepam, d₄-Triazolam, d₆-Zolpidem

4.2 ClinMass® Internal Standard

► Ethylglucuronide and Ethylsulfate

Analytes:

d_5 -Ethylglucuronide, d_5 -Ethylsulfate

| Order No. | Description | Quantity |
|-----------|---------------------------------------------------------------------------------------------------------------------|----------|
| MS8012 | ClinMass® Internal Standard for Ethylglucuronide and Ethylsulfate (in Diluting Solution D) for kit order no. MS8000 | 100 ml |
| MS8112 | ClinMass® Internal Standard for Ethylglucuronide and Ethylsulfate (in Precipitant P) for kit order no. MS8100 | 30 ml |

► Homocysteine

Analytes:

d_8 -Homocysteine

| Order No. | Description | Quantity |
|-----------|----------------------------------------------------------------------------------|----------|
| MS2012 | ClinMass® Internal Standard, lyophil., for Homocysteine for kit order no. MS2000 | 5 ml |
| MS2112 | ClinMass® Internal Standard, lyophil., for Homocysteine for kit order no. MS2100 | 5 ml |

► Immunosuppressants

Analytes:

Ascomycin

Cyclosporine D

Ascomycin, Cyclosporine D, d4-Everolimus

d_{12} -Cyclosporin A, $^{13}C_2$ -Tacrolimus, $^{13}C_3$ -Sirolimus, $^{13}C_2d_4$ -Everolimus

d_{12} -Cyclosporin A, $^{13}C_2$ -Tacrolimus, $^{13}C_3$ -Sirolimus, $^{13}C_2d_4$ -Everolimus

| Order No. | Description | Quantity |
|-----------|---------------------------------------------------------------|----------|
| MS1012 | ClinMass® Internal Standard, lyophil., for Immunosuppressants | 2 µg |

| Order No. | Description | Quantity |
|-----------|---------------------------------------------------------------|----------|
| MS1112 | ClinMass® Internal Standard, lyophil., for Immunosuppressants | 18 µg |

| Order No. | Description | Quantity |
|-----------|---------------------------------------------------------------|----------|
| MS1212 | ClinMass® Internal Standard, lyophil., for Immunosuppressants | 3 ml |

| Order No. | Description | Quantity |
|-----------|---------------------------------------------------------------|----------------------------|
| MS1312 | ClinMass® Internal Standard, lyophil., for Immunosuppressants | 6.25 / 0.25 / 0.5 / 0.5 µg |

| Order No. | Description | Quantity |
|-----------|---------------------------------------------------------------------------------------------------------|----------|
| MS1412 | ClinMass® Internal Standard, lyophil., for Immunosuppressants for kit order nos. MS1100, MS1200, MS1300 | 3 ml |

► Metanephrines

Analytes:

d_3 -Metanephrine, d_4 -3-Methoxytyramine, d_3 -Normetanephrine

| Order No. | Description | Quantity |
|-----------|--------------------------------------------------------------------------------------------|----------|
| MS11012 | ClinMass® Internal Standard for Metanephrines (in Precipitant P) for kit order no. MS11000 | 30 ml |
| MS11112 | ClinMass® Internal Standard for Metanephrines for kit order no. MS11100 | 50 ml |

4.2 ClinMass® Internal Standard

| Order No. | Description | Quantity |
|-----------|------------------------------------------------------------------------------------------------|----------|
| MS5112 | ClinMass® Internal Standard for Methylmalonic Acid (in Precipitant P) for kit order no. MS5100 | 40 ml |

► Methylmalonic Acid

Analytes:
d₃-Methylmalonic Acid

| Order No. | Description | Quantity |
|-----------|-------------------------------------------------------------------------------------------------------------|----------|
| MS99112 | ClinMass® Internal Standard, lyophil., for Mycophenolic Acid for TDM Platform, Add-on Set-order no. MS99100 | 5 x 5 ml |

► Mycophenolic Acid

Analytes:
d₃-Mycophenolic Acid

| Order No. | Description | Quantity |
|-----------|----------------------------------------------------------------------------------------------------------------|----------|
| MS9312 | ClinMass® Internal Standard, lyophil., for Neuroleptics for TDM Platform, Add-on Set-order no. MS9300 | 5 x 5 ml |
| MS9362 | ClinMass® Internal Standard, lyophil., for Neuroleptics for TDM Platform, on-line, Add-on Set order no. MS9350 | 5 ml |

► Neuroleptics

Analytes:
d₅-Amisulpride, d₈-Aripiprazole, d₆-Chlorpromazine, d₆-Chlorprothixene, d₄-Clozapine, d₈-Dehydro-Aripiprazole, d₄-Flupenthixol, d₈-Fluphenazine, d₄-Haloperidol, d₃-Levomepromazine, d₄-Melperone, d₈-Norclozapine, d₃-Olanzapine, d₄-Paliperidone, d₈-Perazine, d₁₀-Pipamperone, d₆-Promethazine, d₆-Prothipendyl, d₈-Quetiapine, d₄-Risperidone, d₄-Sertindole, d₃-Sulpiride, d₃-Thioridazine, d₈-Ziprasidone, d₄-Zuclopenthixol

| Order No. | Description | Quantity |
|-----------|----------------------------------------------------------|----------|
| MS3012 | ClinMass® Internal Standard for Nicotine and Metabolites | 1.5 ml |

► Nicotine and Metabolites

Analytes:
d₃-Nicotine, d₃-Cotinine, d₃-OH-Cotinine

| Order No. | Description | Quantity |
|-----------|--------------------------------------------------------------------|----------|
| MS12012 | ClinMass® Internal Standard for Steroids for kit order no. MS12000 | 10 ml |

► Steroids

Analytes:
d₇-Androstenedione, d₄-Cortisol, d₅-11-Deoxycortisol, d₈-17-Hydroxyprogesterone, d₃-Testosterone, d₅-DHEAS

| Order No. | Description | Quantity |
|-----------|-----------------------------------------------------------------------------------------------|----------|
| MS7012 | ClinMass® Internal Standard for 25-OH-Vitamin D2/D3 for kit order nos. MS7000, MS7100, MS7200 | 30 ml |

► 25-OH Vitamin D2 / D3

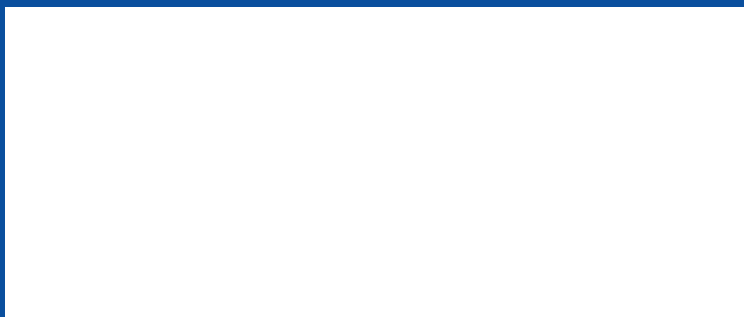
Analytes:
d₆-25-OH-Vitamin D3

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