

HPLC & LC-MS/MS

IVD Complete Kits



**Product Catalogue I
2018/2019**



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 and ISO 9001.

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.

Dr. Gernot Wolfram
General Manager

ClinMass®
TDM Kit System.....6

1 HPLC Complete Kits8

1.1 ClinRep® Diagnostics

1.1.1 Alcoholism
CDT in Serum
▶ manual sample preparation10
▶ on-line Analysis12
▶ automated on-line Analysis.....14

1.1.2 Biogenic Amines
Catecholamines in Plasma.....16
Catecholamines in Urine
▶ manual sample preparation18
▶ with Gilson ASPEC™ XL and
with HTA, Model HT400E20
▶ on-line Analysis22
Metanephrines in Urine
▶ manual sample preparation24
▶ with Gilson ASPEC™ XL and
with HTA, Model HT400E26
Serotonin in Plasma.....28
Serotonin in Urine30
VMA, HVA, 5-HIAA in Urine
▶ manual sample preparation32
▶ with Gilson ASPEC™ XL and
with HTA, Model HT400E34

1.1.3 Hemoglobins
Hemoglobin Variants and β-Thalassemia
Screening in Whole Blood36

1.1.4 Metabolic Diseases
Aromatic Amino Acids in Plasma.....38
Homocysteine in Plasma40
Hydroxyproline in Urine42
Porphyrins Differentiated in Urine44

1.1.5 Oxidative Stress
β-Carotene in Plasma / Serum46
Coenzyme Q10 in Whole Blood /
Plasma / Serum48
Malondialdehyde in
Plasma / Serum50
Vitamin C in Plasma.....52

1.1.6 Vitamin Status
Vitamin A and E in Serum / Plasma54
Vitamin A and E in Serum / Plasma
by UHPLC56
Vitamin B1 in Whole Blood58
Vitamin B2 in Whole Blood60
Vitamin B6 in Plasma / Whole Blood62
Vitamin B1, B2 in Whole Blood and B6
in Plasma / Whole Blood (Combikit)64
25-OH Vitamin D2 / D3 in Plasma
and Serum by HPLC66
25-OH Vitamin D2 / D3 in Plasma
and Serum by HPLC and UHPLC.....68

1.2 ClinRep® TDM for Therapeutic Drug Monitoring

1.2.1 Antiarrhythmics

Amiodarone in Plasma 70

1.2.2 Antiasthmatics

Antiasthmatics in Plasma 72

1.2.3 Antiepileptic Drugs

Antiepileptics in Serum 74

Antiepileptics in Serum /
Plasma, *advanced* 76

Antiepileptics in Serum / Plasma
with UHPLC 78

Lamotrigine and Sulthiame
in Plasma 80

Levetiracetam (Keppra®) in Serum
and Plasma 82

1.2.4 Immunosuppressants

Mycophenolic Acid in Plasma 84

1.2.5 Psychoactive Drugs

Atypical Neuroleptics in Plasma /
Serum, on-line Analysis 86

1.3 ClinTox® HBM for Human Biomonitoring

1.3.1 Benzene and Derivatives

ortho-Cresol and Phenol in Urine 88

Hippuric Acid and Methylhippuric
Acids in Urine 90

t,t-Muconic Acid in Urine 92

1.3.2 PAH Polycyclic Aromatic Hydrocarbons

1-Hydroxypyrene in Urine,
on-line Analysis 94

2 Photometric Complete Kits 96

2.1 ClinEasy® Photometry

2.1.1 Porphyria, Lead Intoxication

5-Aminolevulinic Acid /
Porphobilinogen in Urine 98

Porphobilinogen in Urine 100

Total Porphyrins in Urine 102

3 LC-MS/MS
Complete Kits104

3.1 ClinMass® Diagnostics

3.1.1 Alcoholism
Ethylglucuronide and Ethylsulfate
in Urine, Plasma and Serum106

3.1.2 Biogenic Amines
Free Metanephrines in Plasma
▶ manual sample preparation108
▶ on-line Analysis110

3.1.3 Metabolic Diseases
Homocysteine in Plasma / Serum112
Steroid Hormons in Serum / Plasma114

3.1.4 Vitamin Status
Methylmalonic Acid in Serum /
Plasma / Urine, *advanced*..... 116
25-OH Vitamin D2 / D3 in Plasma
and Serum
▶ on-line Analysis118
▶ automated on-line Analysis.....120

3.2 ClinMass® TDM
Therapeutic Drug Monitoring

3.2.1 Immunosuppressants
Immunosuppressants
in Whole Blood, *advanced*,
▶ on-line Analysis122
▶ automated on-line Analysis.....124

3.2.2 TDM Kit System
Antidepressants in Serum / Plasma126
Antiepileptic Drugs in Serum / Plasma .128
Antimycotics in Serum / Plasma130
Benzodiazepines in Serum / Plasma132
Mycophenolic Acid in Serum / Plasma .134
Neuroleptics in Serum / Plasma136
Tricyclic Antidepressants
in Serum / Plasma.....138

3.2.3 TDM Kit System, on-line
Antidepressants in Serum / Plasma140
Antiepileptic Drugs in Serum / Plasma 142
Antimycotics in Serum / Plasma.....144
Benzodiazepines in Serum / Plasma146
Neuroleptics in Serum / Plasma.....148
Tricyclic Antidepressants
in Serum / Plasma150

3.3 ClinSpot® DBS
Dried Blood Spot Analysis

3.3.1 Newborn Screening (DBS)
Amino Acids and Acylcarnitines
in Dried Blood Spots.....152
Amino Acids and Acylcarnitines in
Dried Blood Spots with Filter-Plates ...154
Homocysteine in Dried Blood Spots ...156

4 LC-MS/MS
Opti Mix and IS158

4.1 ClinMass®
Optimisation Mixes.....160

4.2 ClinMass®
Internal Standards164

Product Catalogue II

Quality Assurance

1 ClinCal® Calibrators

1.1 Analyte Overview.....2

1.2 Product Overview16

2 ClinChek® Controls

2.1 Analyte Overview.....26

2.2 Product Overview42

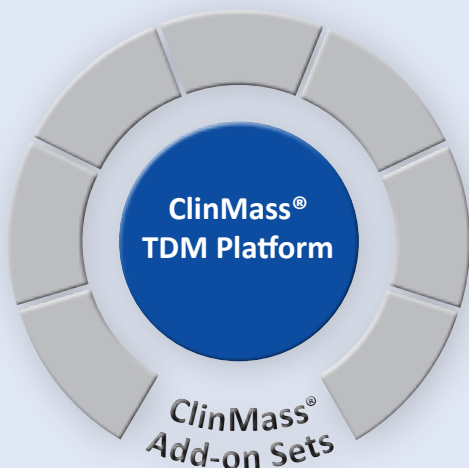
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Please consult the individual manufacturers for specific information.

ClinMass® TDM Kit System

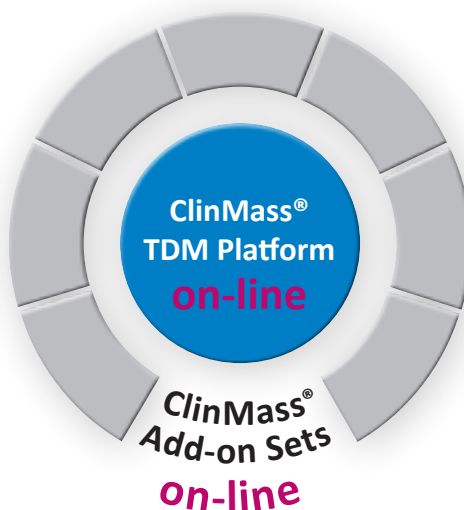
The ClinMass® TDM Kit System is based on our complete kit philosophy and allows to enlarge the spectrum of analytical parameters by simple kit combination. A universal chromatography kit (ClinMass® Platform) can be used for the analysis of several different TDM parameters. For this purpose appropriate 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

**The benefits of the ClinMass®
TDM Kit System**

- ▶ Determination of currently 155 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

1.1 ClinRep®	
Diagnostics	10
1.2 ClinRep® TDM	
Therapeutic Drug	
Monitoring	70
1.3 ClinTox® HBM	
Human Biomonitoring	88

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 this group. 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:	ternary 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
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1. incubate (30 min, 4 °C)
2. centrifuge

Dilution:

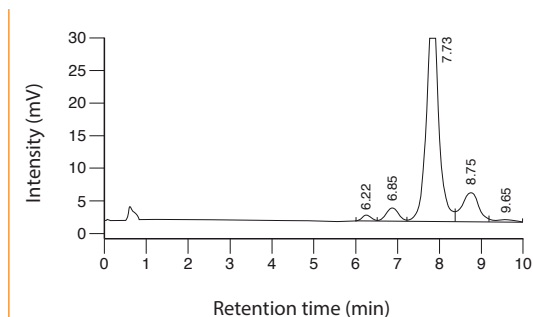
100 µl supernatant	1.0 ml Diluting Solution D
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HPLC Analysis:

Inject 400 - 500 µl

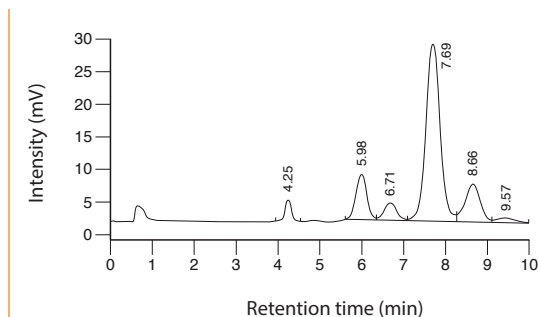
1.1.1. Alcoholism

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:		
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

CDT in Serum

► on-line Analysis

This ClinRep® Complete Kit is designed for the fast analysis of CDT with on-line SPE HPLC. 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

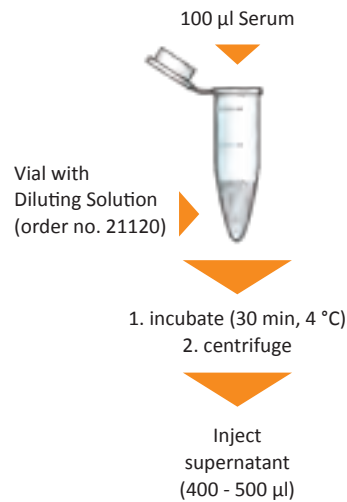
LOD:	0.1 %*
LLOQ:	0.3 %*
Intraassay precision:	4.5 %
Interassay precision:	3.9 %

* 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

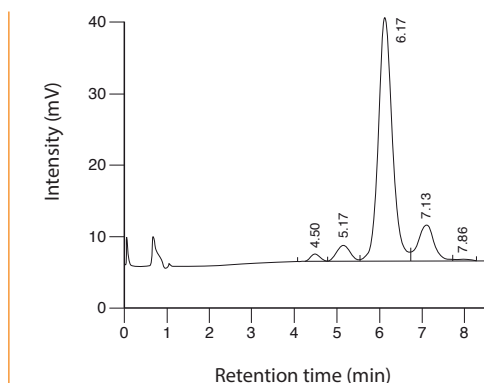
Sample Pretreatment



**One step
sample pretreatment!**

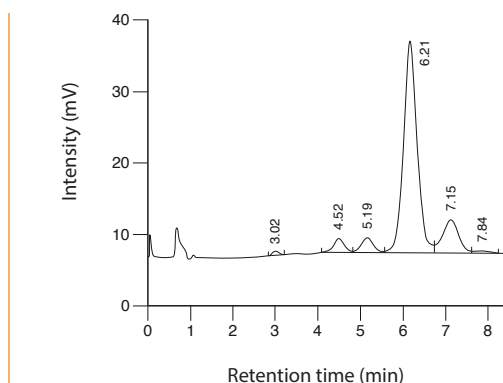
1.1.1. Alcoholism

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:		
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	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	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

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 HPLC. 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-, ..., hexa-sialotransferrin). This applies in particular for di-sialotransferrin, which is the defined analyte by this group. 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
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1. incubate (30 min, 4 °C)
2. centrifuge

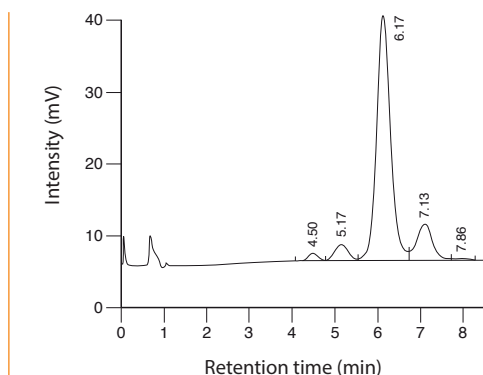


on-line Analysis:

Inject 400 µl

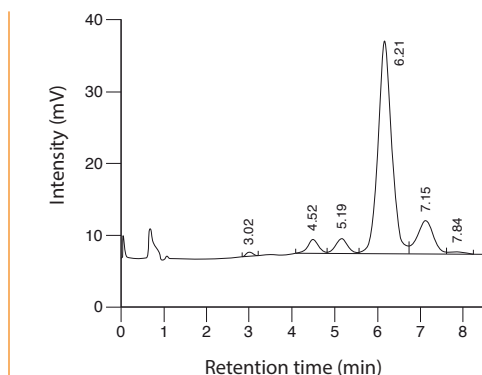
1.1.1. Alcoholism

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
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:		
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	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	4 pcs. each
FW3000	Fixed-Wavelength-VIS-Detector (460 nm), complete	1 pce.
RC2002	Sodium-Hypochlorite-Solution (5 %)	12 ml
ClinChek® Controls:		
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 (or ambient)

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

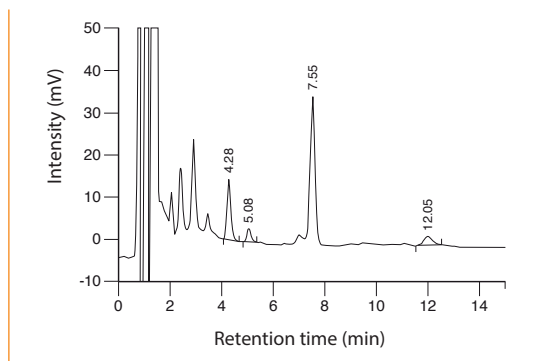
HPLC Analysis:

Inject 40 µl



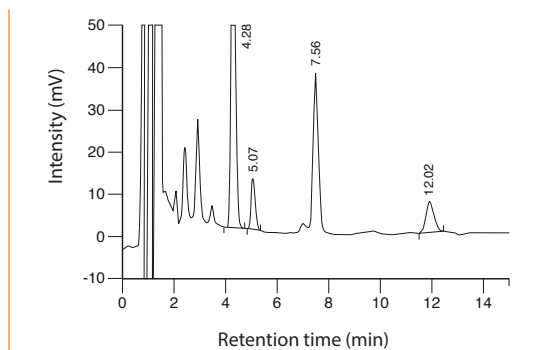
1.1.2. Biogenic Amines

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

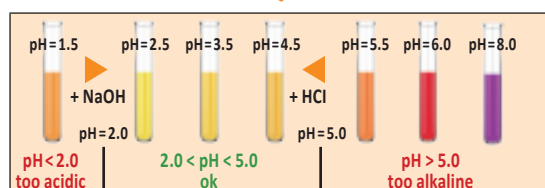
- Safe and convenient pH-adjustment
- Robust chromatography
- Detection limit: 1 µg/l



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)

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

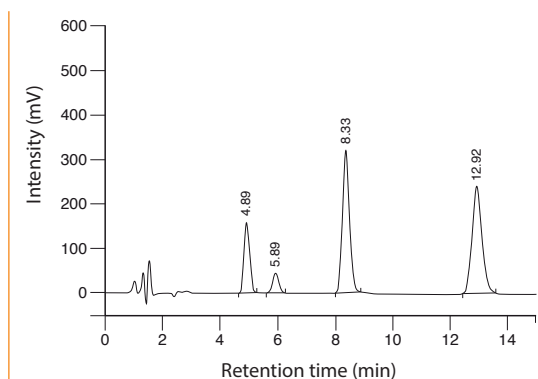
3 ml urine	5 ml Stab. Reagent S (contains colour indic.)	30 µl Internal Standard IS
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Inject 20 μ l

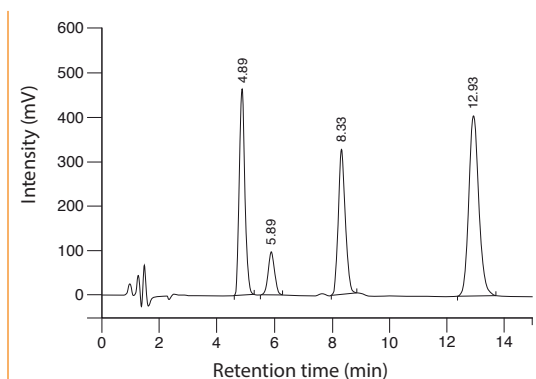
1.1.2. Biogenic Amines

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™ XL
- ▶ with HTA, Model HT400E

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 two ClinRep® Complete Kits for automated sample preparation with robotic systems from Gilson and HTA. Kits for 100 and 500 assays are available for each system.

- 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

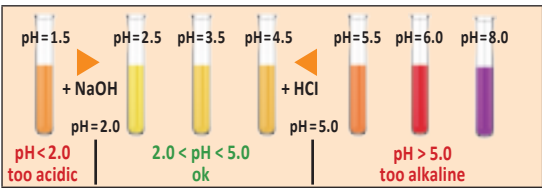
Sample Preparation*

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™ XL

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™ XL. The corresponding data for the HT400E are available on request.

1.1.2. Biogenic Amines

Ordering Information

Order No.	Description	Quantity
2200	ClinRep® Complete Kit for Catecholamines in Urine with Gilson ASPEC™ XL 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™ XL 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
2400	ClinRep® Complete Kit for Catecholamines in Urine with HTA, Model HT400E for 100 assays	1 pce.
Kit components (order no. 2400):		
1210	Mobile Phase	1000 ml
2011	Standard Solution	10 ml
2012	Internal Standard IS	2 x 2012 (2 x 3 ml)
2013	Urine Calibrator, lyophil.	5 x 8 ml
2420	Sample Preparation Columns	2 x 2420 (2 x 50 pcs.)
2421	Stabilising Reagent S	250 ml
2424	Eluting Reagent E	250 ml
FK6401	Sample vials, clear glass, 4ml	2 x FK6401 (2 x 100 pcs.)
	Manual	1 pce.
	Quick Reference	1 pce.
2500	ClinRep® Complete Kit for Catecholamines in Urine with HTA, Model HT400E for 500 assays	1 pce.
Kit components (order no. 2500):		
	5-fold amount of kit components with order no. 2400 (1210, 2011, ..., FK6401)	5 x 2400
Components for 2200, 2300, 2400, 2500		
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 HPLC 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

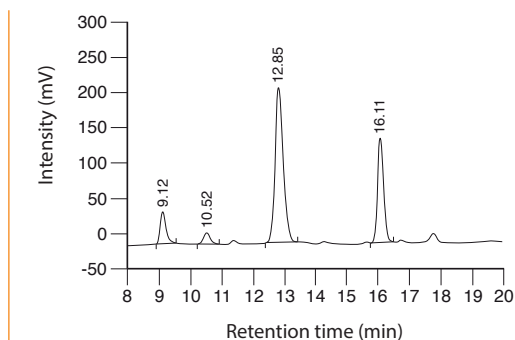
on-line Analysis:

Inject 50 µl

NE: Norepinephrine
E: Epinephrine
D: Dopamine

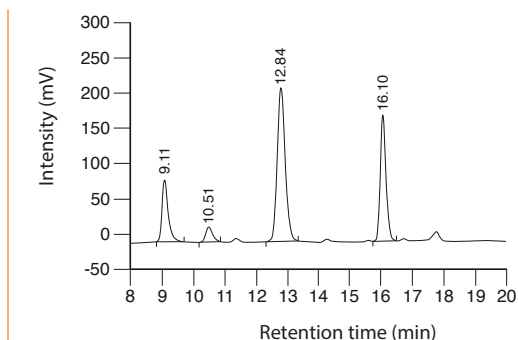
1.1.2. Biogenic Amines

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 (FD), lyophil.	5 x 5 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 Column	4 pcs.
2130	Analytical Column with test chromatogram	1 pce.
2131	SPE-Column	1 pce.
FK5810	PEEK capillary connector	1 pce.
FK5820	Stainless steel prefilter holder	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.
FK7330	Endfittings	2 pcs.
FK7340	Sealings and sieves	4 pcs. each
FK7350	Endstoppers	2 pcs.
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, this test kit of RECIPE 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

Isocratic Pump:	flow rate: 1.0 ml/min
Injection vol. / int.:	20 μl / 17 min
EC-Detector:	pot.:650 mV, sen.: 50 nA
HPLC-Thermostat:	30 $^{\circ}\text{C}$

Sample Preparation

Hydrolysis:

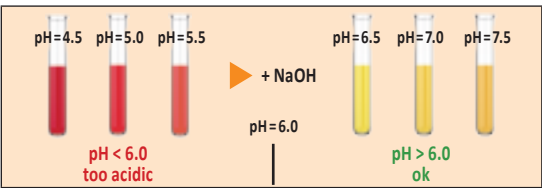
1 ml urine	20 μl Internal Standard IS
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1. adjust pH to 0.5 - 1.0
2. incubate (30 min, 90 - 100 $^{\circ}\text{C}$)

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



wash (HPLC water and Washing Solution W)

Extraction:

Apply the whole sample on the sample preparation column

Elution:

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

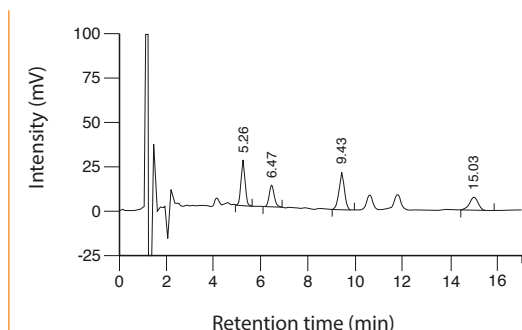
collect the eluate

HPLC Analysis:

Inject 20 μl

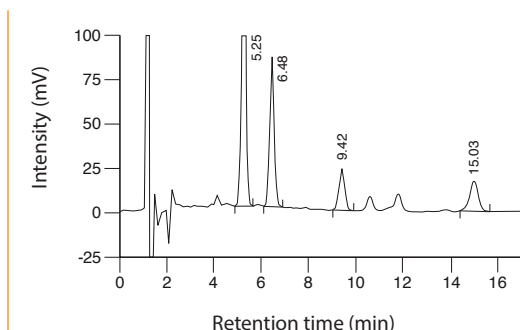
1.1.2. Biogenic Amines

ClinChek® Urine Control, Level I



Normetanephrine: 5.26 min, Metanephrine: 6.47 min,
IS: 9.43 min, 3-Methoxytyramine: 15.03 min

ClinChek® Urine Control, Level II



Normetanephrine: 5.25 min, Metanephrine: 6.48 min,
IS: 9.42 min, 3-Methoxytyramine: 15.03 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):		
4010	Mobile Phase	1000 ml
4011	Standard Solution	10 ml
4012	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:		
4030	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

Metanephrines in Urine

- ▶ with Gilson ASPEC™ XL
- ▶ with HTA, Model HT400E

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 two ClinRep® Complete Kits for automated sample preparation with robotic systems from Gilson and HTA. Kits for 100 and 500 assays are available for each system.

- 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:

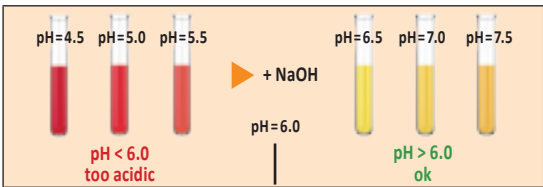
1 ml urine	20 µl Internal Standard IS
------------	----------------------------

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™ XL

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™ XL. The corresponding data for the HT400E are available on request.

1.1.2. Biogenic Amines

Ordering Information

Order No.	Description	Quantity
4100	ClinRep® Complete Kit for Metanephrines in Urine with Gilson ASPEC™ XL for 100 assays	1 pce.
Kit components (order no. 4100):		
4010	Mobile Phase	1000 ml
4011	Standard Solution	10 ml
4012	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™ XL 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
4300	ClinRep® Complete Kit for Metanephrines in Urine with HTA, Model HT400E for 100 assays	1 pce.
Kit components (order no. 4300):		
4010	Mobile Phase	1000 ml
4011	Standard Solution	10 ml
4012	Internal Standard IS	3 ml
4013	Urine Calibrator, lyophil.	5 x 8 ml
4320	Sample Preparation Columns	2 x 4320 (2 x 50 pcs.)
4022	Diluting Solution D	400 ml
4323	Washing Solution W	500 ml
4124	Eluting Reagent E	250 ml
4125	Stabilising Reagent S	80 ml
FK6401	Sample vials, clear glass, 4ml	2 x FK6401 (2 x 100 pcs.)
	Manual	1 pce.
	Quick Reference	1 pce.
4400	ClinRep® Complete Kit for Metanephrines in Urine with HTA, Model HT400E for 500 assays	1 pce.
Kit components (order no. 4400):		
	5-fold amount of kit components with order no. 4300 (4010, 4011, ..., FK6401)	5 x 4300
Components for 4100, 4200, 4300, 4400		
Start Accessories:		
4030	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. More over, serotonin is produced in excess by carcinoid tumors. Here, the determination of serotonin, together with its metabolite 5-HIAA, is used to confirm or rule out the tumor. The RECIPE test kit allows for a quick and sensitive determination of serotonin from platelet-rich plasma, platelet-poor plasma and serum. For the determination from urine an additional test kit is available.

- 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
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1. add 200 µl Precipitant P
2. centrifuge

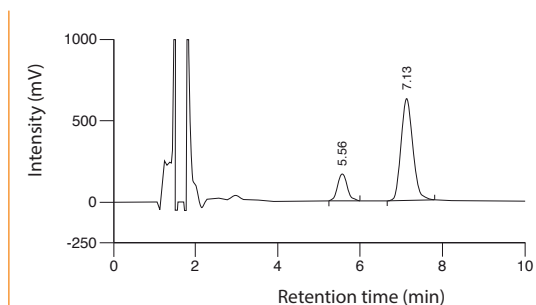


HPLC Analysis:

Inject 20 µl

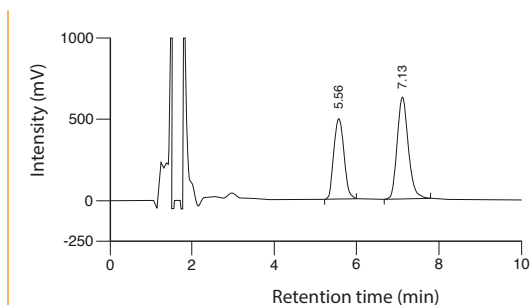
1.1.2. Biogenic Amines

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 test kit of RECIPE provides a highly selective sample preparation and guarantees a reliable chromatography.

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



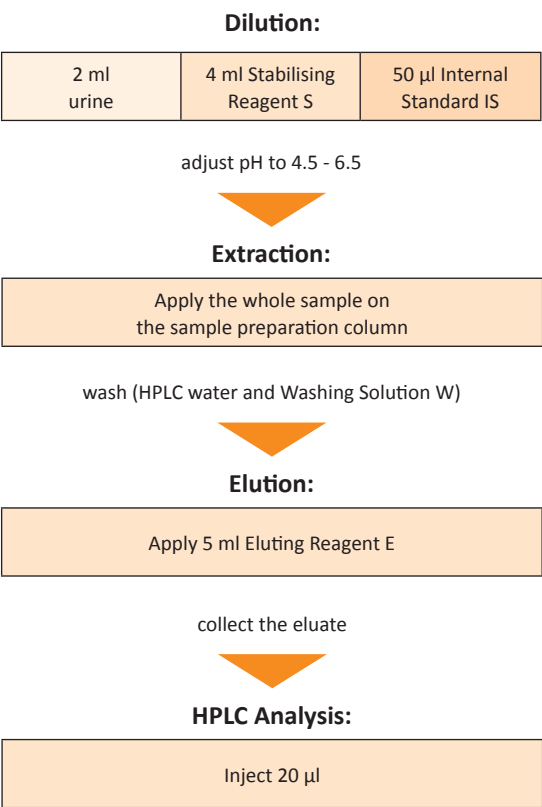
Test Data

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

HPLC Parameters

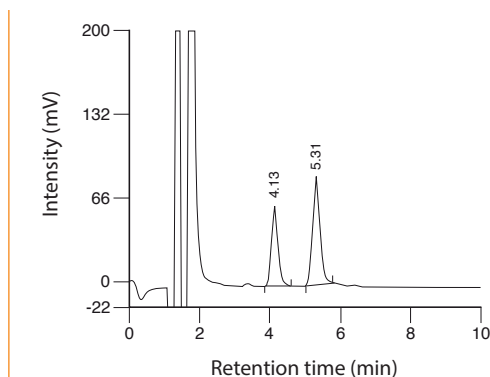
Pump:	isocratic pump, flow rate: 1.0 ml/min
Injection volume:	20 µl
Injection interval:	10 min
EC-Detector:	potential: 450 mV, sensitivity: 50 nA
HPLC-Thermostat:	30 °C

Sample Preparation



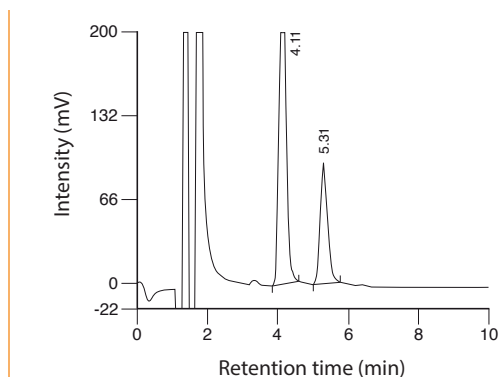
1.1.2. Biogenic Amines

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

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. This ClinRep® Complete Kit from RECIPE 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
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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

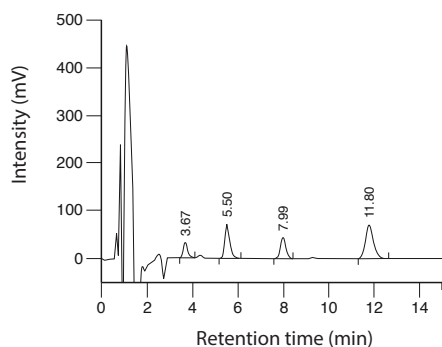
collect the eluate

HPLC Analysis:

Inject 20 µl

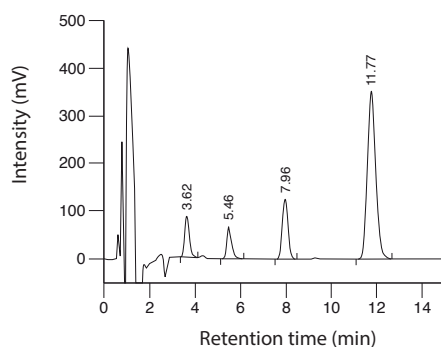
1.1.2. Biogenic Amines

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, lyophil.	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

VMA, HVA and 5-HIAA in Urine

- ▶ with Gilson ASPEC™ XL
- ▶ with HTA, Model HT400E

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 two ClinRep® Complete Kits for automated sample preparation with robotic systems from Gilson and HTA. Kits for 100 and 500 assays are available for each system.

- 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™ XL

Addition of IS:

50 µl urine	1 ml Internal Standard IS
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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™ XL. The corresponding data for the HT400E are available on request.



1.1.2. Biogenic Amines

Ordering Information

Order No.	Description	Quantity
3100	ClinRep® Complete Kit for VMA, HVA, 5-HIAA in Urine with Gilson ASPEC™ XL 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™ XL 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
3300	ClinRep® Complete Kit for VMA, HVA, 5-HIAA in Urine with HTA, Model HT400E for 100 assays	1 pce.
Kit components (order no. 3300):		
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
3320	Sample Preparation Columns	2 x 3320 (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)
FK6401	Sample vials, clear glass, 4ml	2 x FK6401 (2 x 100 pcs.)
FK6402	Sample vial without cap, PP, 1.5 ml	100 pcs.
	Manual	1 pce.
	Quick Reference	1 pce.
3400	ClinRep® Complete Kit for VMA, HVA, 5-HIAA in Urine with HTA, Model HT400E for 500 assays	1 pce.
Kit components (order no. 3400):		
	5-fold amount of kit components with order no. 3300 (3010, 3011, ..., FK6402)	5 x 3300
Components for 3100, 3200, 3300, 3400		
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 for 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 to 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 µl
Injection interval:	8 min
UV/VIS-Detector:	415 nm
HPLC-Thermostat:	23 °C

Sample Preparation

Hemolysis:

5 µl venous blood	1.25 ml Hemolysis Reagent H
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incubate (10 min, ambient temp.)

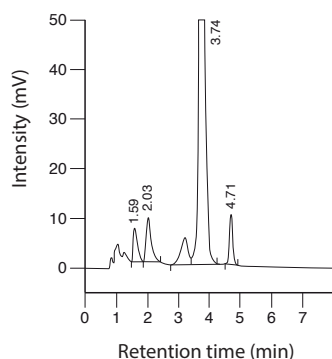


HPLC Analysis:

Inject 20 µl

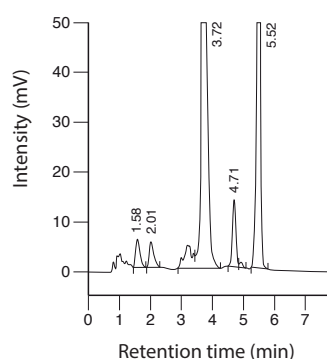
1.1.3. Hemoglobins

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	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 tryptophane, 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 tryptophane 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

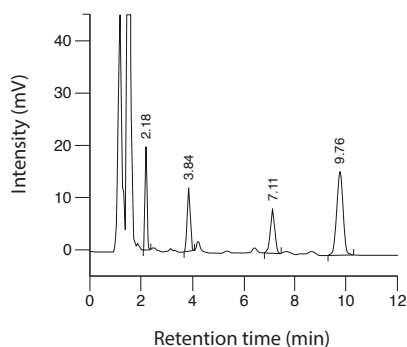


HPLC Analysis:

Inject 20 µl of the supernatant

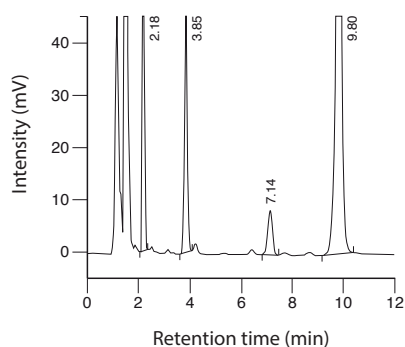
1.1.4. Metabolic Diseases

ClinChek® Plasma Control, Level I



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

ClinChek® Plasma Control, Level II



Tyrosine: 2.18 min, Phenylalanine: 3.85 min, IS: 7.14 min,
Tryptophane: 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	Precipitant P with Internal Standard (contained in vials for sample preparation)	2 x 10020 (50 x 0.5 ml)
	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	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 µmol/l
Recovery:	95 - 105 %
LOD:	0.5 µmol/l
LLOQ:	1 µmol/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
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Precipitation:

150 µl reduced sample	100 µl Reagent B
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centrifuge

Derivatisation:

50 µl supernatant	100 µl Reagent C	50 µl Reagent D
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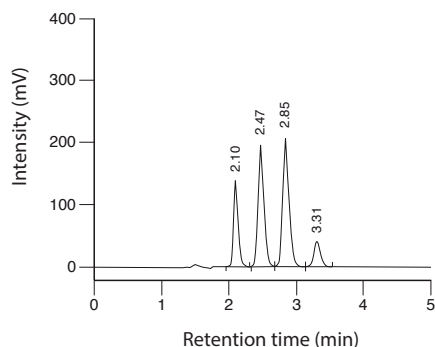
incubate (60 min, 60 °C)

HPLC Analysis:

Inject 20 µl

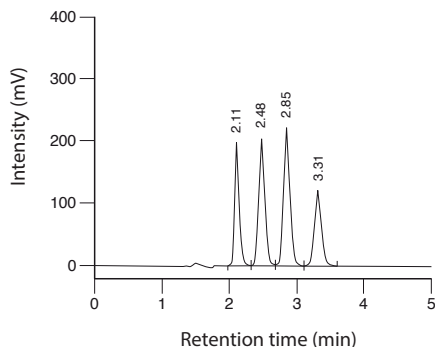
1.1.4. Metabolic Diseases

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	1 pce.
FK5821	Replacement filter for stainless steel prefilter holder	10 pcs.
ClinChek® Controls:		
23080	Plasma Control, lyophil., Level I	10 x 3 ml
23081	Plasma Control, lyophil., Level II	10 x 3 ml
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



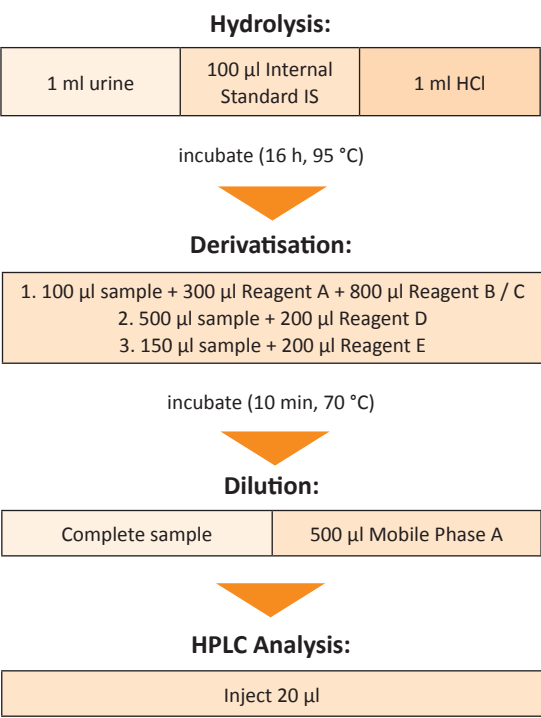
Test Data

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

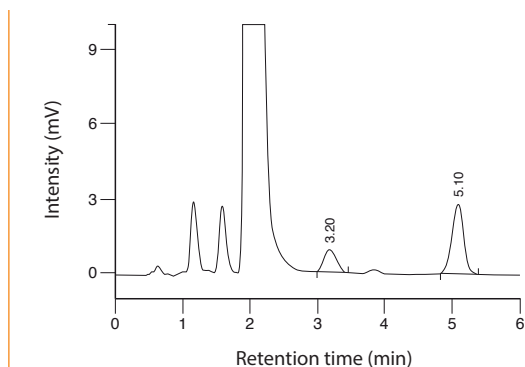
Pump:	binary gradient pump, flow rates: 1.2, 1.4 ml/min
Injection volume:	20 µl
Injection interval:	8 min
UV/VIS-Detector:	471 nm
HPLC-Thermostat:	60 °C

Sample Preparation



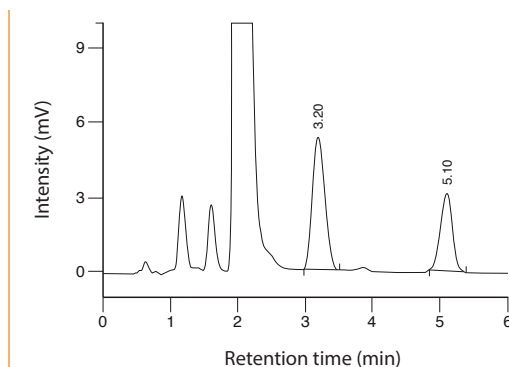
1.1.4. Metabolic Diseases

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	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

Porphyrins 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
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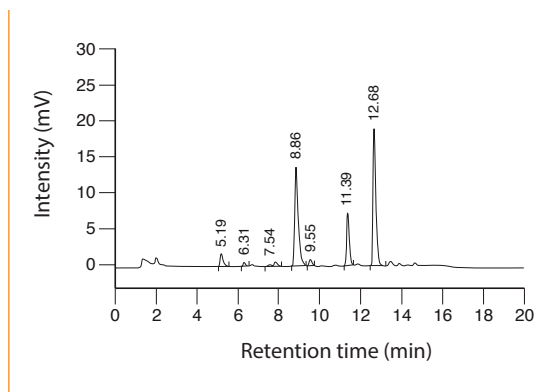
centrifuge

HPLC Analysis:

Inject 20 µl of the supernatant

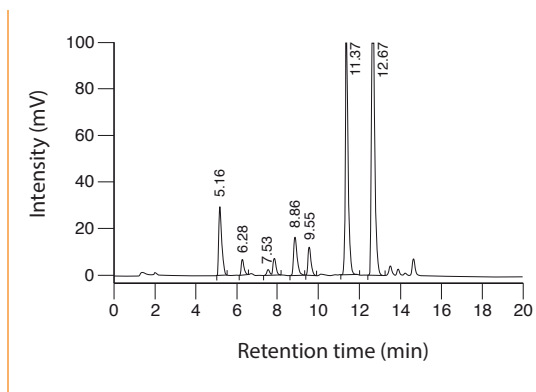
1.1.4. Metabolic Diseases

ClinChek® Urine Control, Level I



Uroporphyrin I: 5.19 min, Heptacarboxyporphyrin I: 6.31 min, Hexacarboxyporphyrins (Iac and Iab 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 Iab 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	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

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 µl
Injection interval:	10 min
UV-Detector:	450 nm
HPLC-Thermostat:	30 °C

Sample Preparation

Precipitation:

100 µl sample	200 µl Precipitant P (contains IS)	100 µl Stabilising Reagent S
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mix, centrifuge

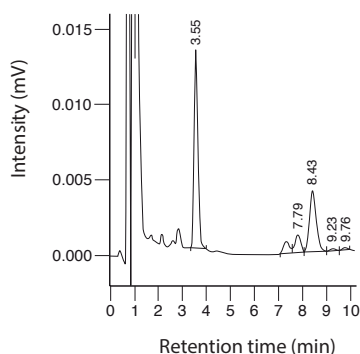
HPLC Analysis:

Inject 100 µl



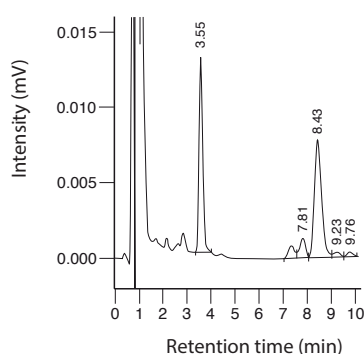
1.1.5. Oxidative Stress

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	20 ml
30013	Plasma Calibrator, lyophil.	5 x 0.5 ml
30014	Test Solution, lyophil.	3 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	1 pce.
FK5821	Replacement filter for stainless steel prefilter holder	10 pcs.
ClinChek® Controls:		
30080	Plasma Control, lyophil., Level I	10 x 2 ml
30081	Plasma Control, lyophil., Level II	10 x 2 ml
30082	Plasma Control, lyophil., Level I, II	2 x 5 x 2 ml

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 for 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

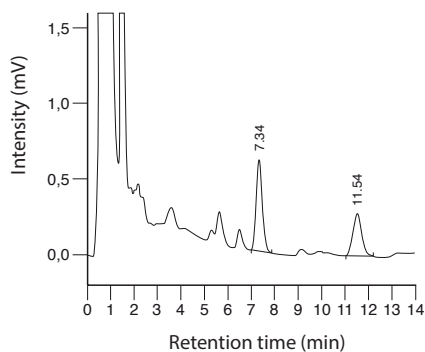
mix, centrifuge

HPLC Analysis:

Inject 30 µl of the supernatant

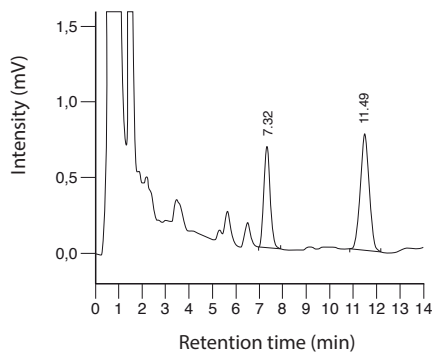
1.1.5. Oxidative Stress

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	1 pce.
FK5821	Replacement filter for stainless steel prefilter holder	10 pcs.
ClinChek® Controls:		
31080	Plasma Control, lyophil., Level I	10 x 2 ml
31081	Plasma Control, lyophil., Level II	10 x 2 ml
31082	Plasma Control, lyophil., Level I, II	2 x 5 x 2 ml

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



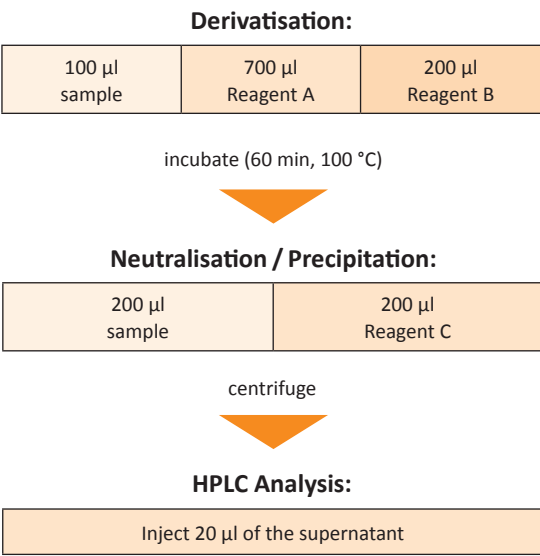
Test Data

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

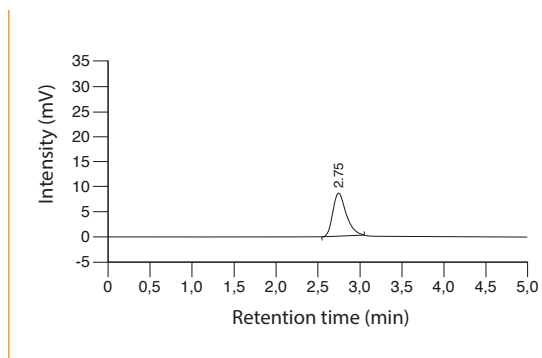
Pump:	isocratic pump, flow rate: 0.8 ml/min
Injection volume:	20 µl
Injection interval:	5 min
Fluorescence detector:	515 nm (exc.), 553 nm (em.)
HPLC-Thermostat:	30 °C

Sample Preparation



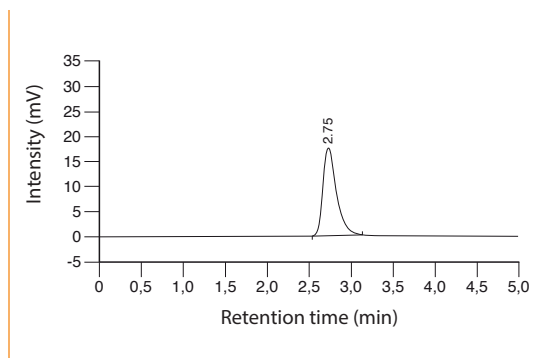
1.1.5. Oxidative Stress

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 Column	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	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

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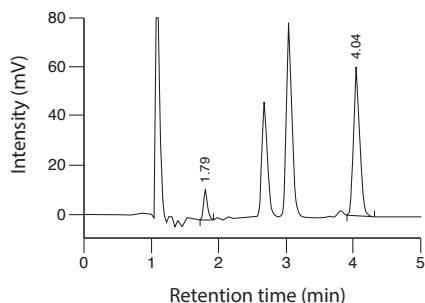
1. incubate (10 min, + 4°C)
2. centrifuge

HPLC Analysis:

Inject 20 µl of the supernatant

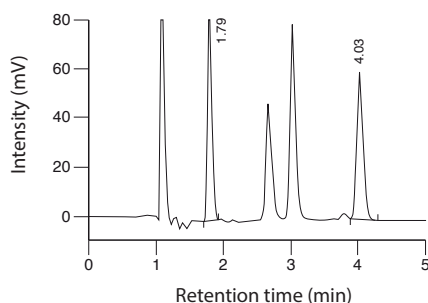
1.1.5. Oxidative Stress

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 Column	5 pcs.
FK5810	PEEK tubing (connection of prefilter and column)	1 pce.
FK5820	Stainless steel prefilter holder	1 pce.
FK5821	Replacement filter for stainless steel prefilter holder	10 pcs.
ClinChek® Controls:		
28080	Serum Control, lyophil., Level I	10 x 0.5 ml
28081	Serum Control, lyophil., Level II	10 x 0.5 ml
28082	Serum Control, lyophil., Level I, II	2 x 5 x 0.5 ml

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



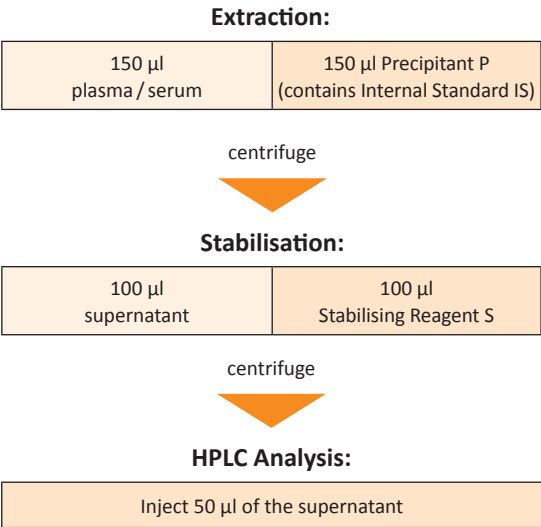
Test Data

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

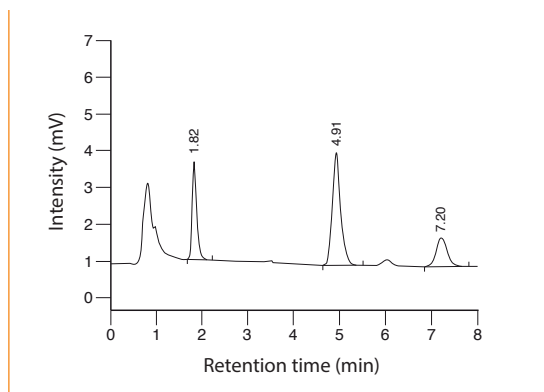
Pump:	isocratic pump, flow rate: 1.5 ml/min
Injection volume:	50 μ l
Injection interval:	8 min
UV-Detector:	325 / 295 nm
HPLC-Thermostat:	30 °C

Sample Preparation



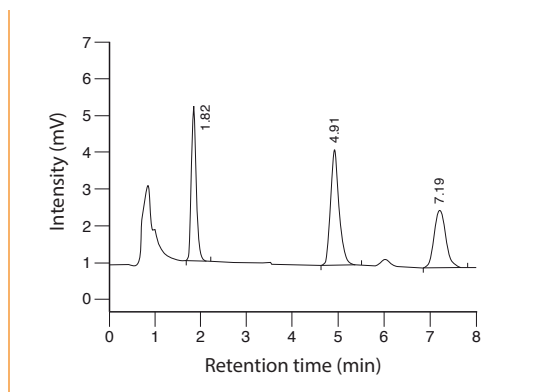
1.1.6. Vitamin Status

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	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

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



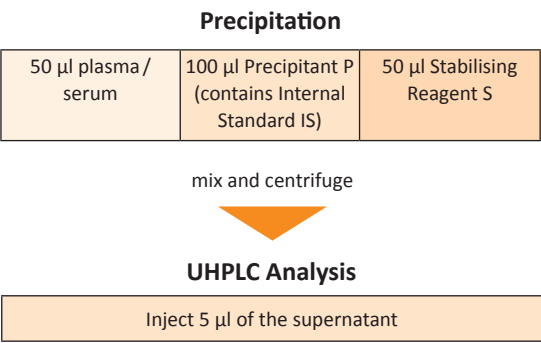
Test Data

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

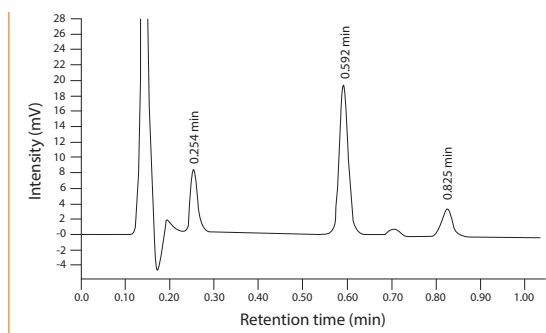
Pump:	isocratic pump, flow rate: 0.8 ml/min
Injection volume:	5 µl
Injection interval:	1.2 min
UV-Detector:	325 / 295 nm
Column heater:	30 °C

Sample Preparation



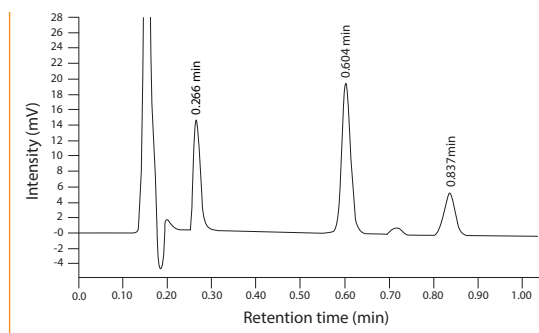
1.1.6. Vitamin Status

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

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
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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
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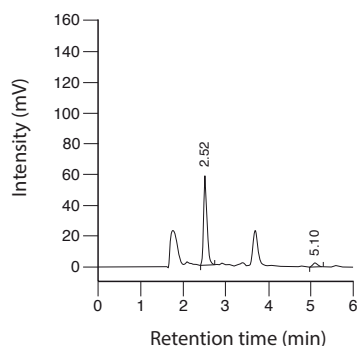
add 100 µl Reagent E

HPLC Analysis:

Inject 50 µl of the supernatant

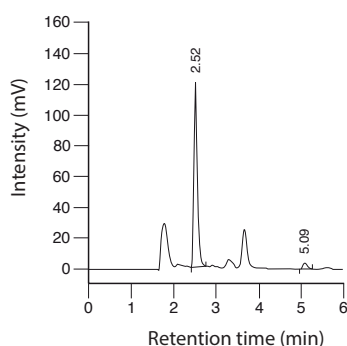
1.1.6. Vitamin Status

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 Column	5 pcs.
FK2000	ClinLab® Peristaltic pump	1 pce.
FK2001	Replacement tubing 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	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

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, enzyme functions as well as for the fatty acid and amino acid synthesis. The under-supply 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 features short time for analysis (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
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1. add 500 µl Stabilising Reagent S
2. centrifuge

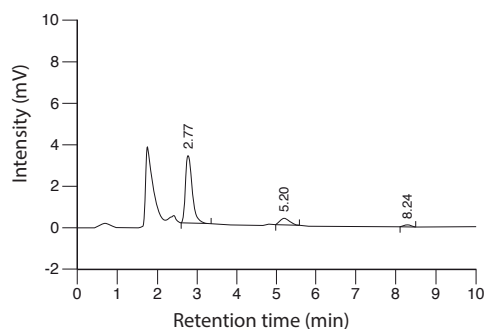


HPLC Analysis:

Inject 50 µl of the supernatant

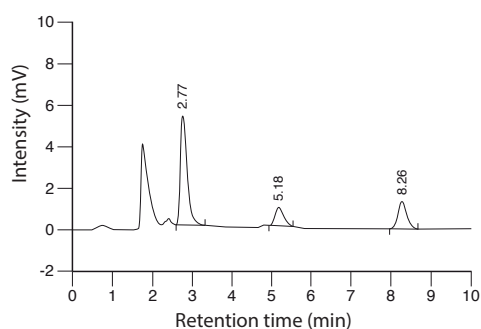
1.1.6. Vitamin Status

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 Column	5 pcs.
FK5810	PEEK-tubing (connection of prefilter and column)	1 pce.
FK5820	Stainless steel prefilter holder	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

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 for 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

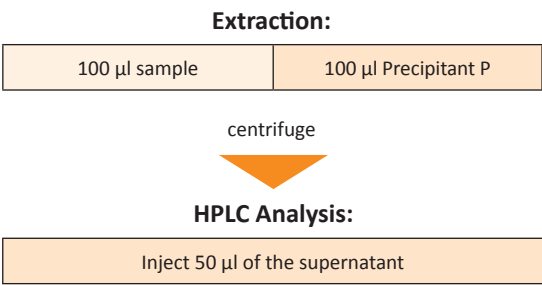
Test Data Determination from plasma / from whole blood

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

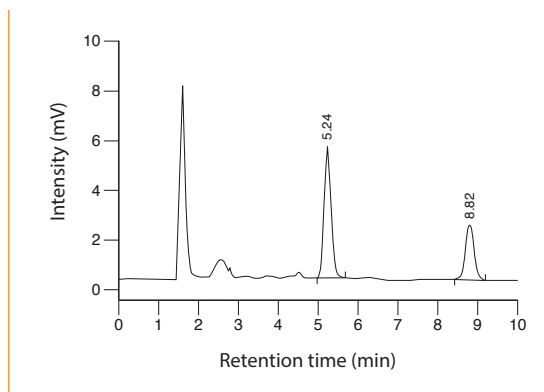
Pump:	isocratic pump, flow rate: 1.0 ml/min
Pump (Reagent N):	flow rate: 0.2 ml/min
Injection volume:	50 µl
Injection interval:	10 min
Fluorescence detector:	370 nm (exc.), 470 nm (em.)
Temperature:	25 °C (or ambient)

Sample Preparation



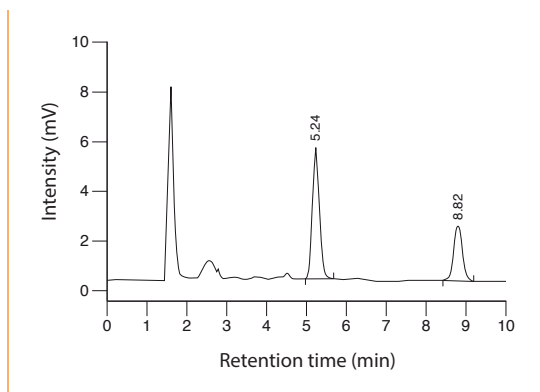
1.1.6. Vitamin Status

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 Column	5 pcs.
FK2000	ClinLab® Peristaltic pump	1 pce.
FK2001	Replacement tubing 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	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

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 preparation 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 Column	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	ClinLab® Peristaltic pump	1 pce.
FK2001	Replacement tubing 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	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

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);	
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);	
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);	

* Mobile phase not included

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

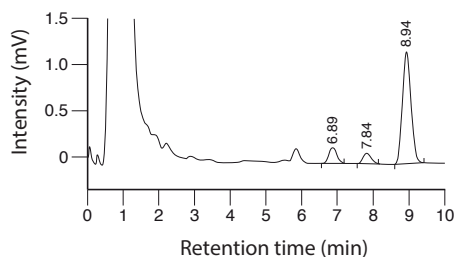
mix, centrifuge

HPLC Analysis:

Inject 50 µl of the supernatant

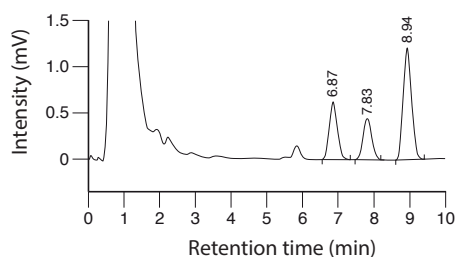
1.1.6. Vitamin Status

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 with Reagent, lyophil.	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 Column	5 pcs.
FK5810	PEEK tubing (connection of prefilter and column)	1 pce.
FK5820	Stainless steel prefilter holder	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

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

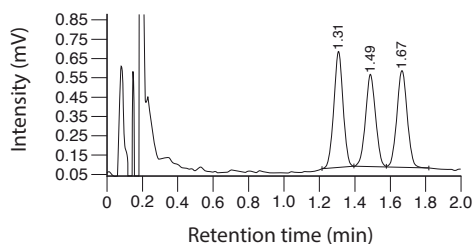
mix, centrifuge

UHPLC Analysis:

Inject 5 µl of the supernatant

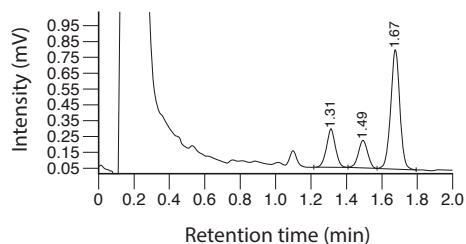
1.1.6. Vitamin Status

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

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

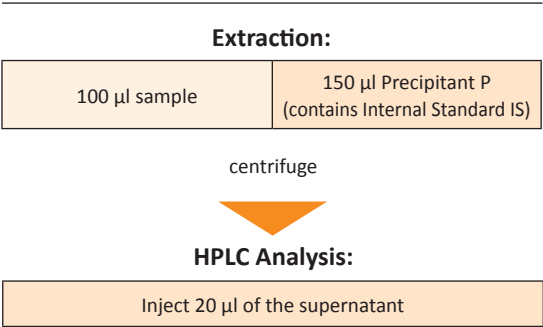
Test Data

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 %

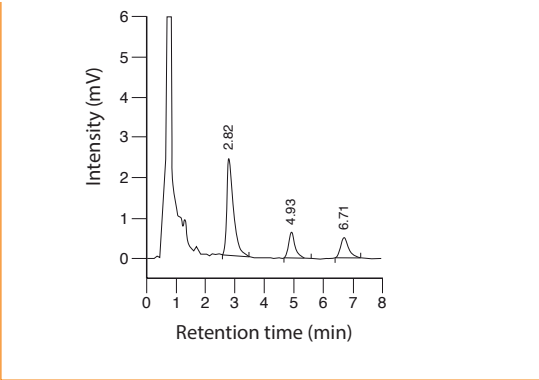
HPLC Parameters

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

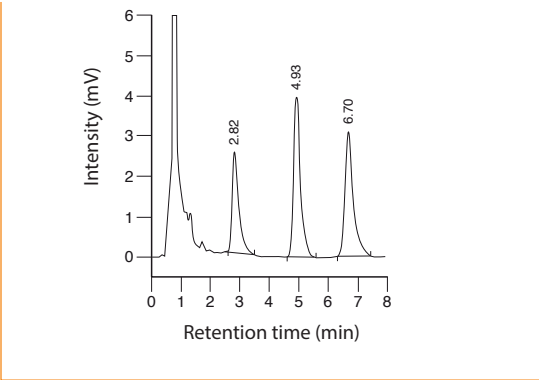


ClinChek® Serum Control, Level I



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 Column	5 pcs.
FK5810	PEEK tubing (connection of prefilter and column)	1 pce.
FK5820	Stainless steel prefilter holder	1 pce.
FK5821	Replacement filter for stainless steel prefilter holder	10 pcs.
ClinChek® Controls:		
20080	Serum Control, lyophil., Level I	10 x 3 ml
20081	Serum Control, lyophil., Level II	10 x 3 ml
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



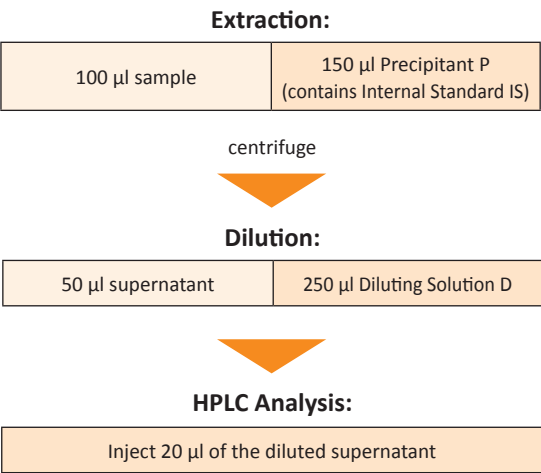
Test Data

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 %

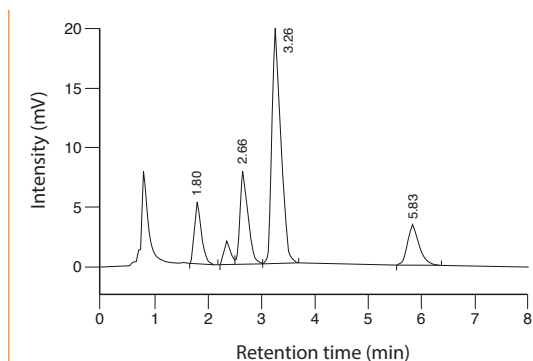
HPLC Parameters

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

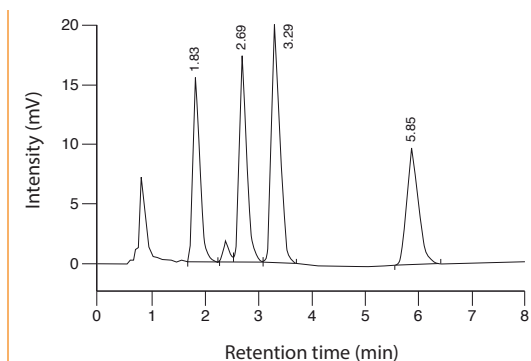


ClinChek® Plasma Control, Level I



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	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)



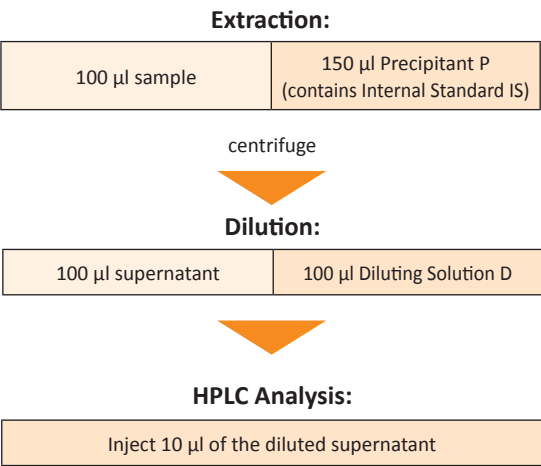
Test Data

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 %

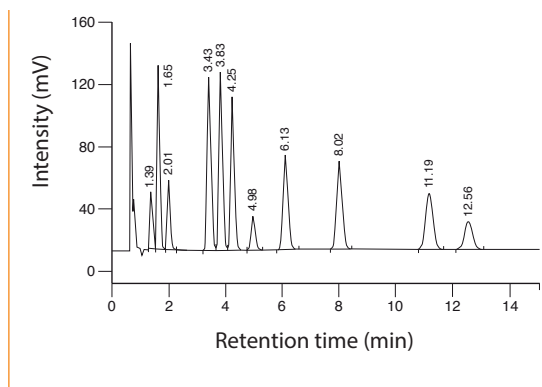
HPLC Parameters

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

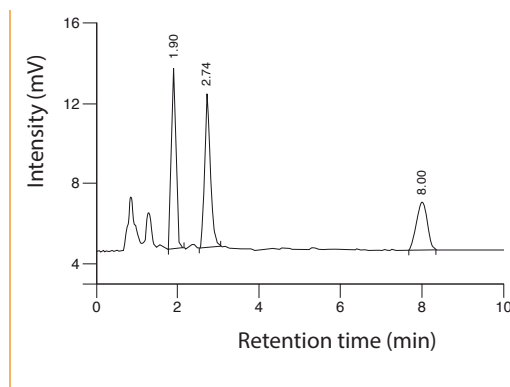


ClinChek® Serum Control, Level II, recorded at 205 nm:



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 Column	5 pcs.
FK5810	PEEK tubing (connection of prefilter and column)	1 pce.
FK5820	Stainless steel prefilter holder	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)
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centrifuge



Dilution:

150 µl supernatant	250 µl Diluting Solution D
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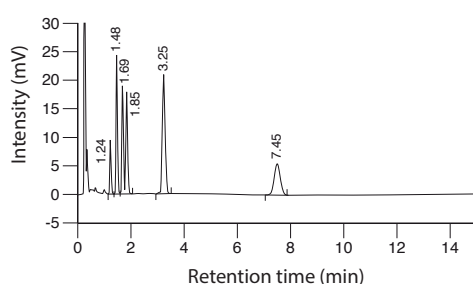
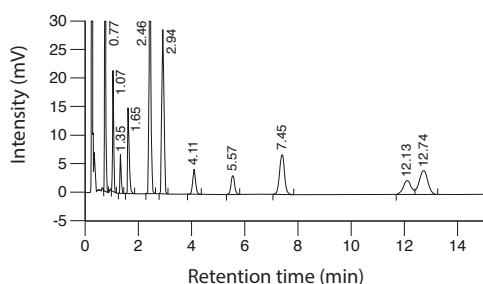


HPLC Analysis:

Inject 10 µl of the diluted supernatant

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

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



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

Lacosamide: 1.24 min, Zonisamide: 1.48 min,
Felbamate: 1.69 min, Rufinamide: 1.85 min,
N-Desmethylethosuximide: 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	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-desmethylnethsuximide, 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

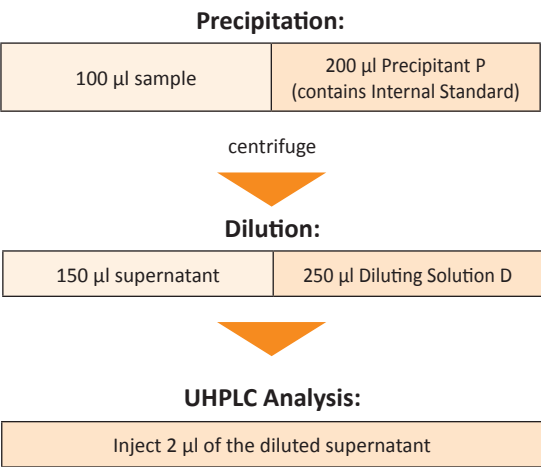
Test Data

The test data are available on request.

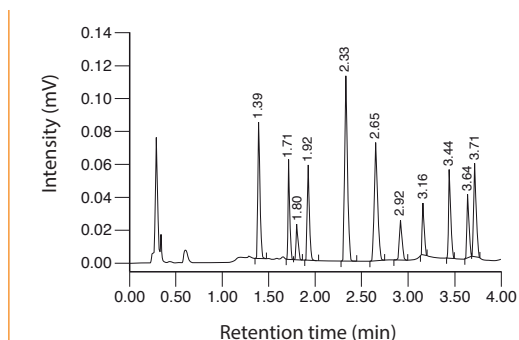
UHPLC Parameters

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

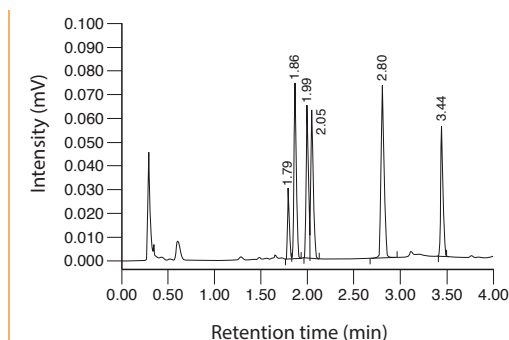


ClinChek® Serum Control, Level II (order no. 14081)



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-Desmethylnethsuximide: 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)
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centrifuge



Dilution:

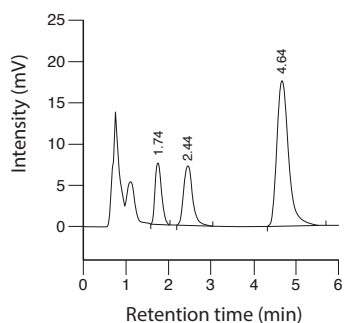
100 µl supernatant	100 µl Diluting Solution D
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HPLC Analysis:

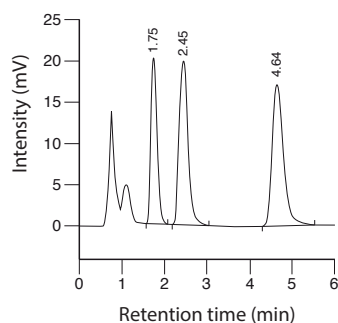
Inject 20 µl of the diluted supernatant

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 Column	5 pcs.
FK5810	PEEK tubing (connection of prefilter and column)	1 pce.
FK5820	Stainless steel prefilter holder	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

Levetiracetam (Keppra®) in Serum and Plasma

The RECIPE analytical method for levetiracetam completes the RECIPE kit portfolio for the analysis of antiepileptic drugs (AED). 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)
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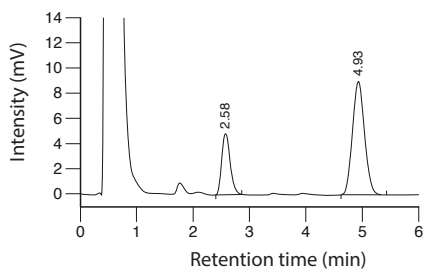


HPLC Analysis:

Inject 20 µl

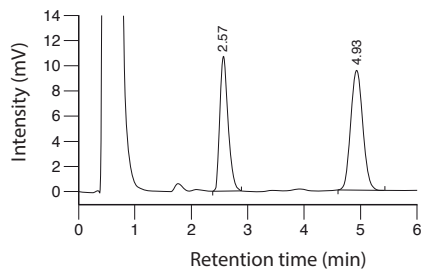
* Conditioning with Conditioning Reagent C and Washing Solution W1

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)
15522	Washing Solution W1	2 x 15522 (2 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	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

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
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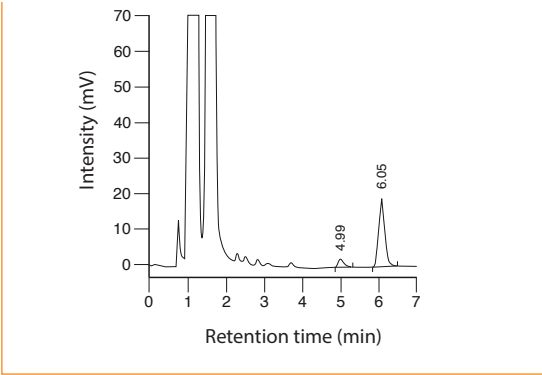
centrifuge



HPLC Analysis:

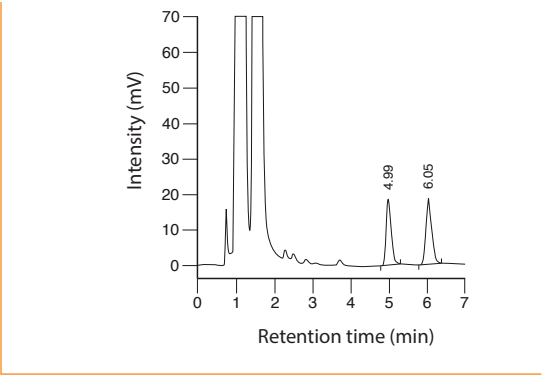
Inject 50 µl of the supernatant

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	1 pce.
FK5821	Replacement filter for stainless steel prefilter holder	10 pcs.
ClinChek® Controls:		
29080	Plasma Control, lyophil., Level I	10 x 3 ml
29081	Plasma Control, lyophil., Level II	10 x 3 ml
29082	Plasma Control, lyophil., Level III	10 x 3 ml
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, that allows for 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:

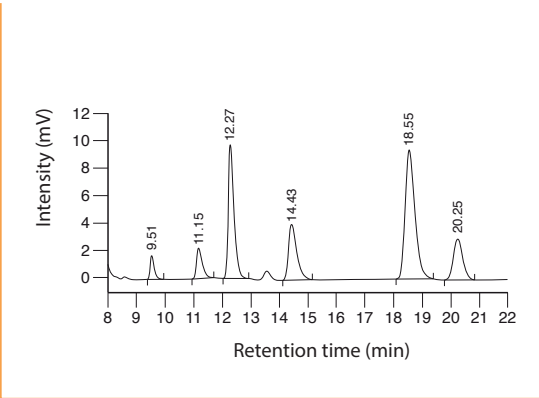
- A:** Add 20 µl Internal Standard IS/ml sample
B: Add 10 µl Internal Standard IS/ml sample

centrifuge

on-line Analysis:

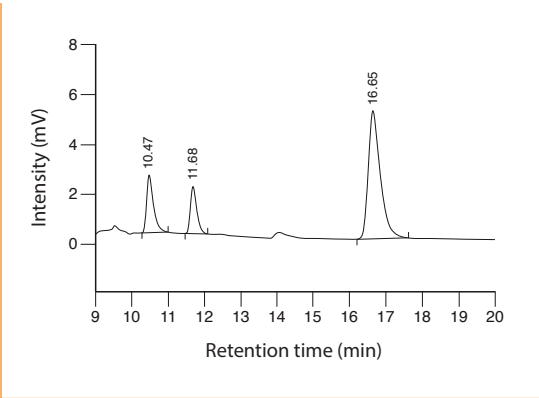
- A:** Inject 250 µl
B: Inject 750 µl

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 Column	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	4 pcs. each
ClinChek® Controls:		
40080	Plasma Control, lyophil., Level I	10 x 3 ml
40081	Plasma Control, lyophil., Level II	10 x 3 ml
40082	Plasma Control, lyophil., Level I, II	2 x 5 x 3 ml
40180	Plasma Control, lyophil., for Risperidone and Paliperidone, Level I	10 x 5 ml
40181	Plasma Control, lyophil., for Risperidone and Paliperidone, Level II	10 x 5 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
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incubate (37 °C, 2 - 24 h)

Extraction:

Transfer the whole sample to a conditioned sample preparation column
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wash (2 x 2 ml Reagent B)

Elution:

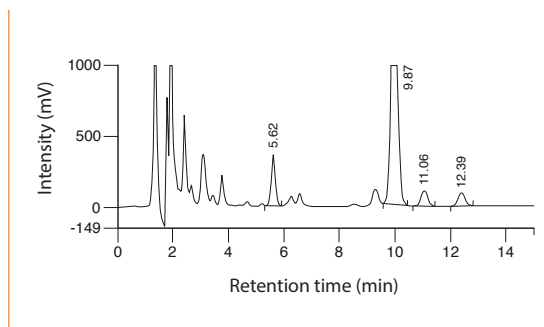
Elute with 2 ml Reagent A

collect the eluate

HPLC Analysis:

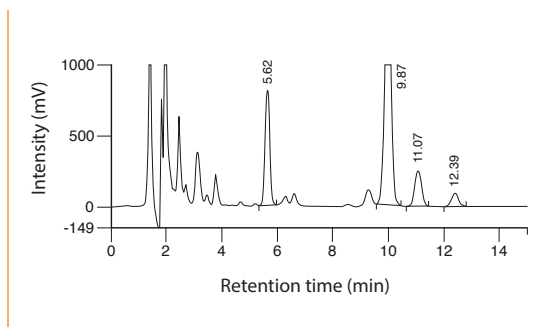
Inject 10 - 20 µl

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	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
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Extraction:

Transfer the whole sample to a conditioned sample preparation column

wash (2 x 2 ml Reagent B)

Elution:

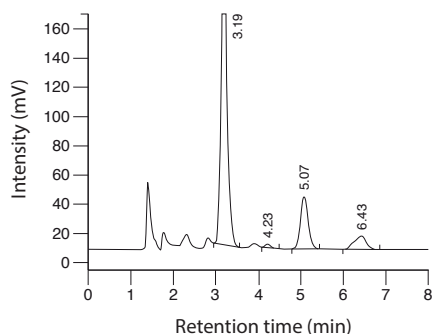
Elute with 2 ml Reagent A

collect the eluate

HPLC Analysis:

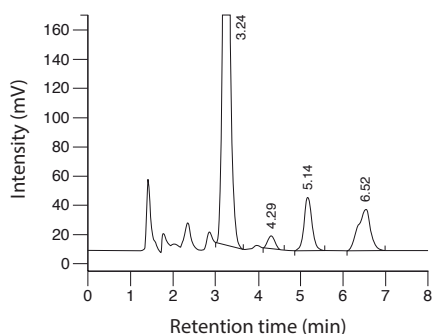
Inject 20 µl

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	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
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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

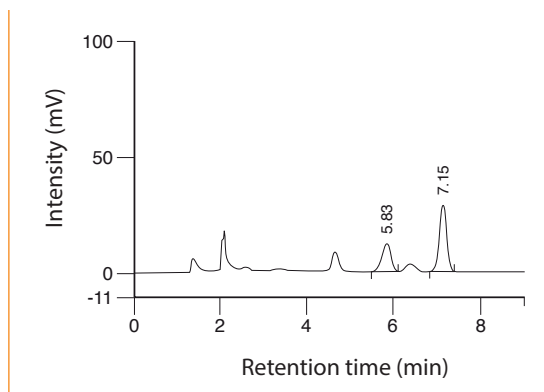


HPLC Analysis:

Inject 50 µl

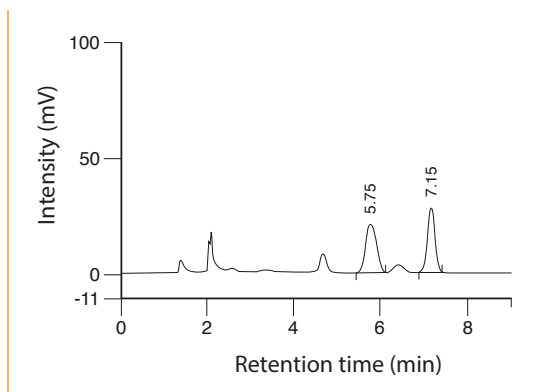
1.3.1. Benzene and Derivatives

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

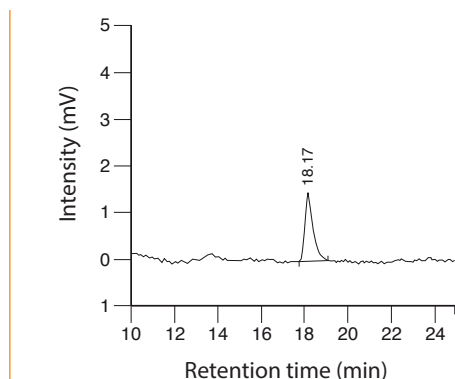


on-line Analysis:

Inject 250 µl

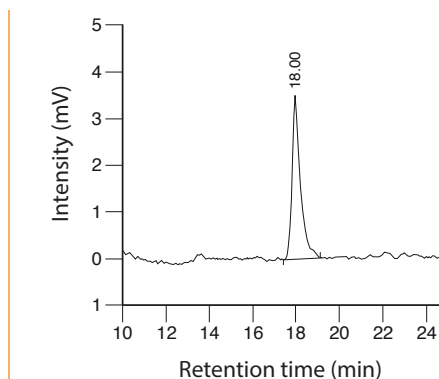
1.3.2. PAH Polycyclic Aromatic Hydrocarbons

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 Column	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	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:	> 90 %
LOD:	0.6 mg/l
LLOQ:	0.8 mg/l
Intraassay precision:	5-ALA: 3.4 % PBG: 5.2 %
Interassay precision:	5-ALA: 4.6 % PBG: 6.4 %

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

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
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:	> 90 %
LOD:	0.6 mg/l
LLOQ:	0.8 mg/l
Intraassay precision:	5.2 %
Interassay precision:	6.4 %

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



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
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:

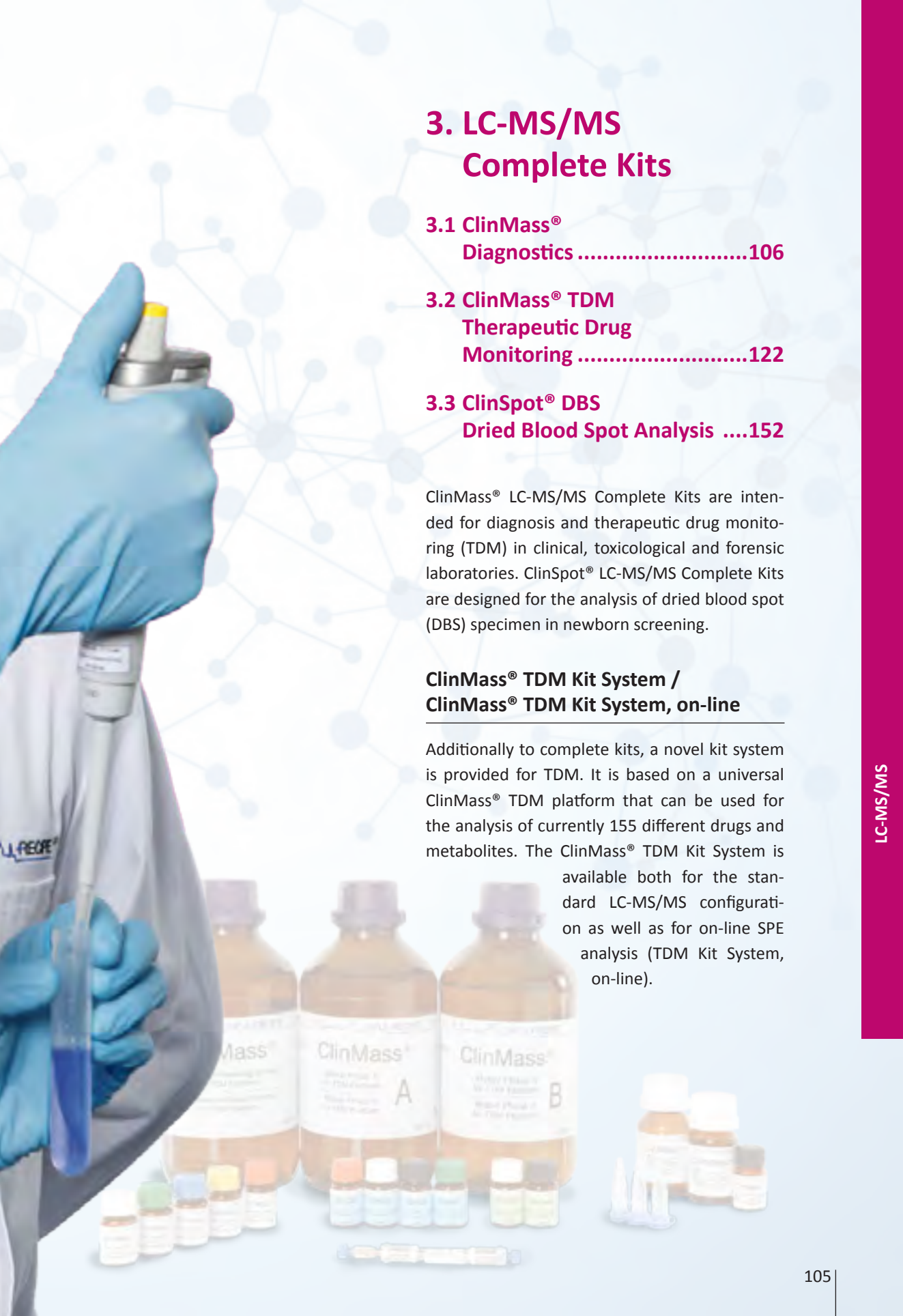
Photometric measurement



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
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mix, centrifuge

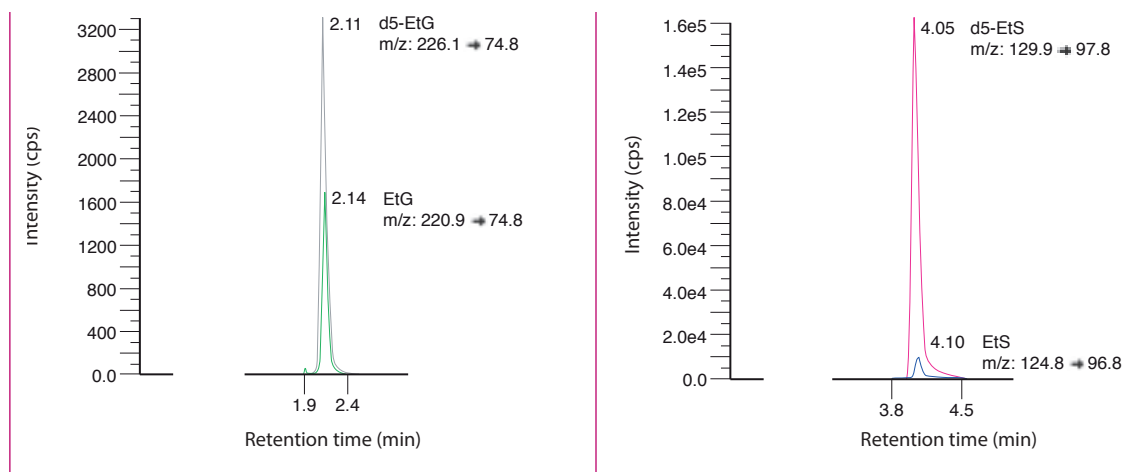
Dilution:

50 µl supernatant	500 µl Diluting Solution D
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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 PFM (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

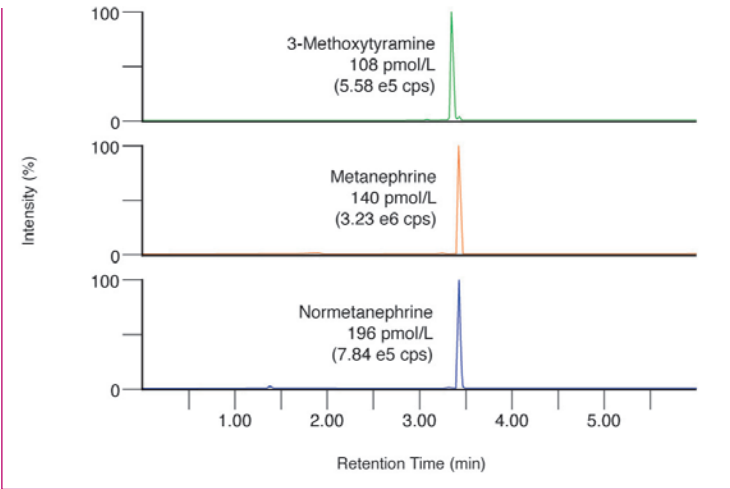
collect the eluate

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	1000 ml
MS11112	Internal Standard IS	50 ml
MS11013	Serum Calibrator Set, lyophil. (Level 0 - 4)	5 x 1 x 3 ml
MS11014	Optimisation Mix	2 ml
MS11120	Sample Preparation Columns	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
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 PFM (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

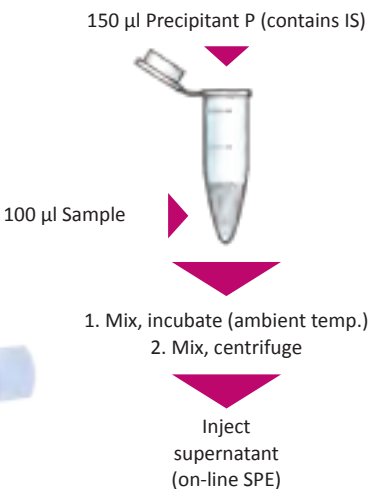
LC-Parameters

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

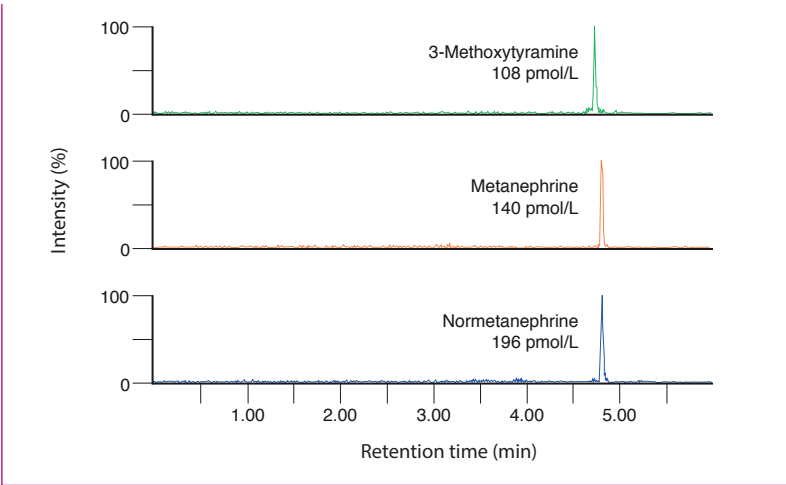
MS-Parameters

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:

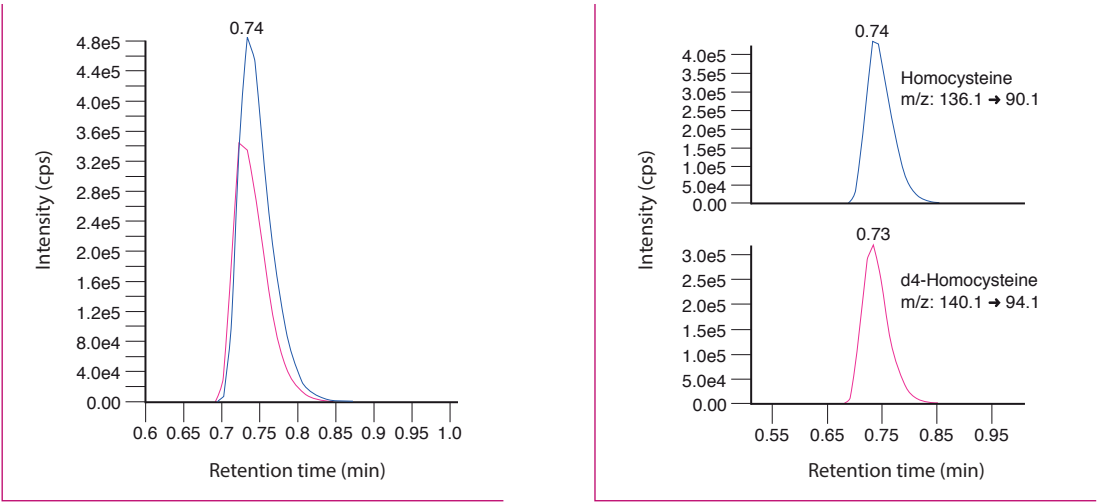
200 µl Reagent B

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:		
23080	Plasma Control, lyophil., Level I	10 x 3 ml
23081	Plasma Control, lyophil., Level II	10 x 3 ml
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. Mainly, they are 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 Pretreatment

Precipitation:

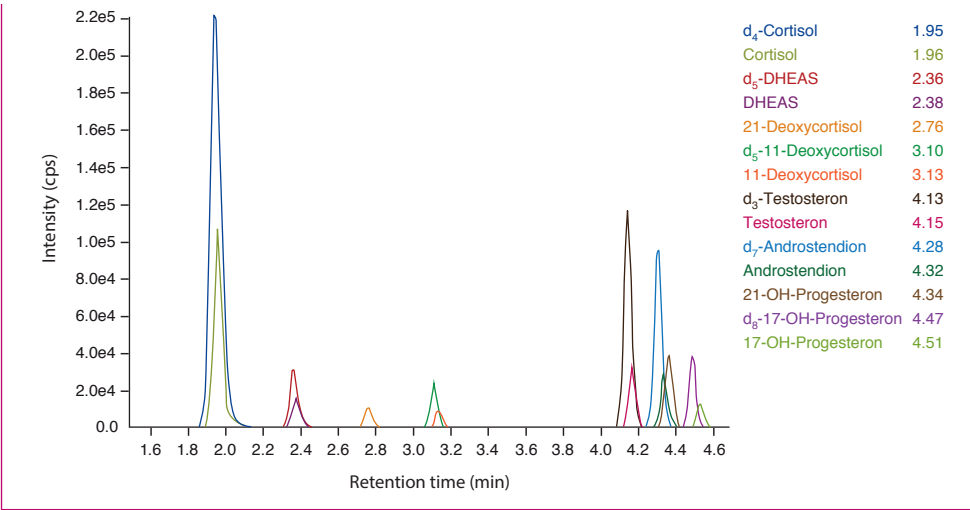
75 µl Mixture IS/ P	50 µl sample (calibrator, control, patient)
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1. mix, precipitate
2. mix, centrifuge

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	100 pcs.
MS12021	Precipitant P	5 ml
	Manual	
Additional components:		
MS12014	Optimix	2 x 1 x 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 separated reliably. 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)
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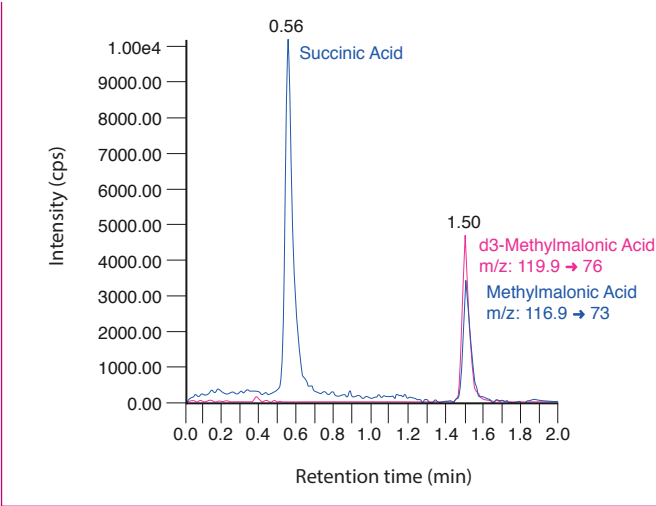
mix and centrifuge

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	200 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:		
MS5080	Serum Control, lyophil., Level I	10 x 2 ml
MS5081	Serum Control, lyophil., Level II	10 x 2 ml
MS5082	Serum Control, lyophil., Level I, II	2 x 5 x 2 ml

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 (APCI), 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

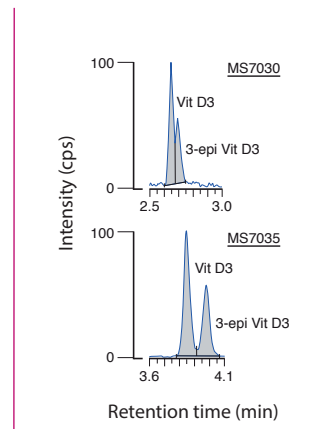
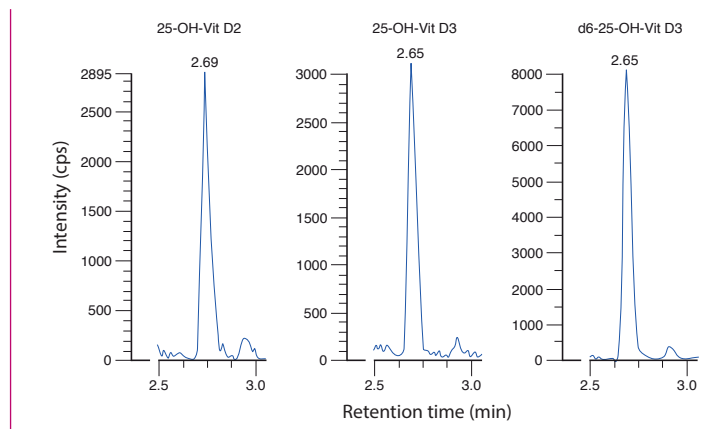


on-line Analysis:

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

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 enables 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	IS Internal Standard	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	P Precipitant	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	IS Internal Standard	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	P Precipitant	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	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

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



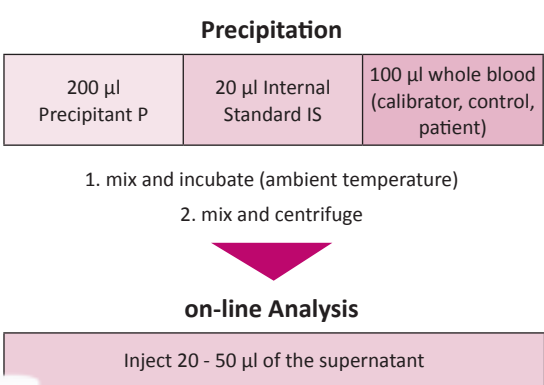
Test Data

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)

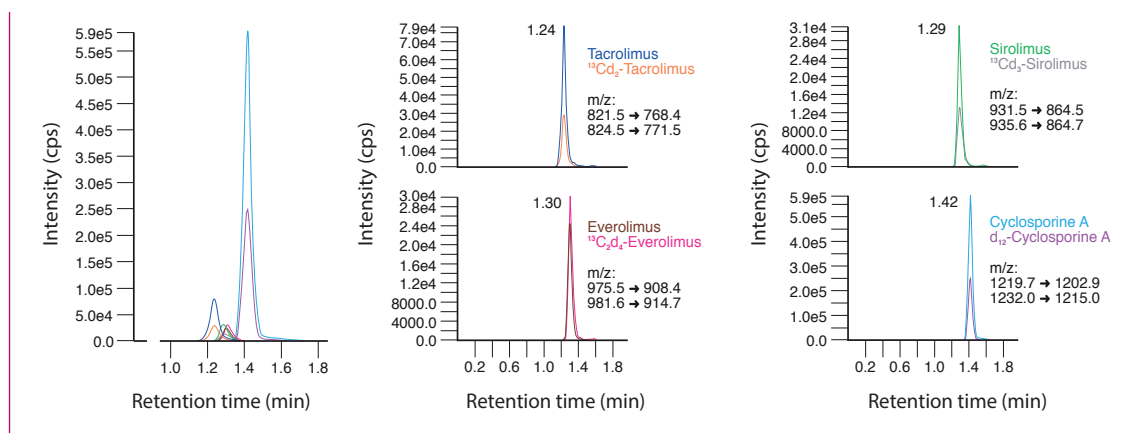
LC-MS/MS Parameters

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



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, <i>advanced</i>, 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:		
MS1006	Reagent MP	8 ml
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 Column	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

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

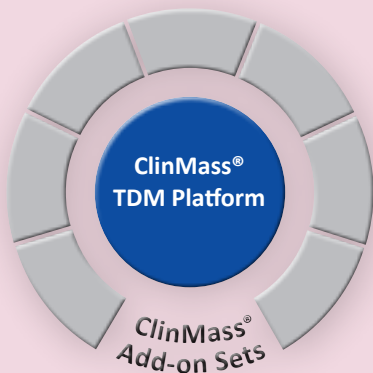
Ordering Information

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	IS Internal Standard, lyophil.	9 x MS1412 (9 x 3 ml)
FK6511	96-Well Plates (1200 µl)	3 x FK6511 (3 x 5 pcs.)
MS1021	P Precipitant	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	IS Internal Standard, 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	P Precipitant	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 37 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 37 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

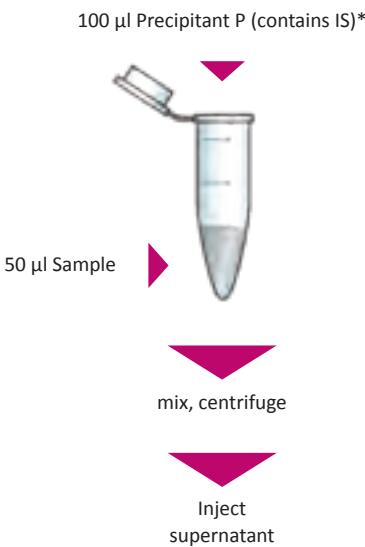
Column heater: 40 °C

MS-Parameters

Ion source: ESI, positive

MS/MS mode: MRM

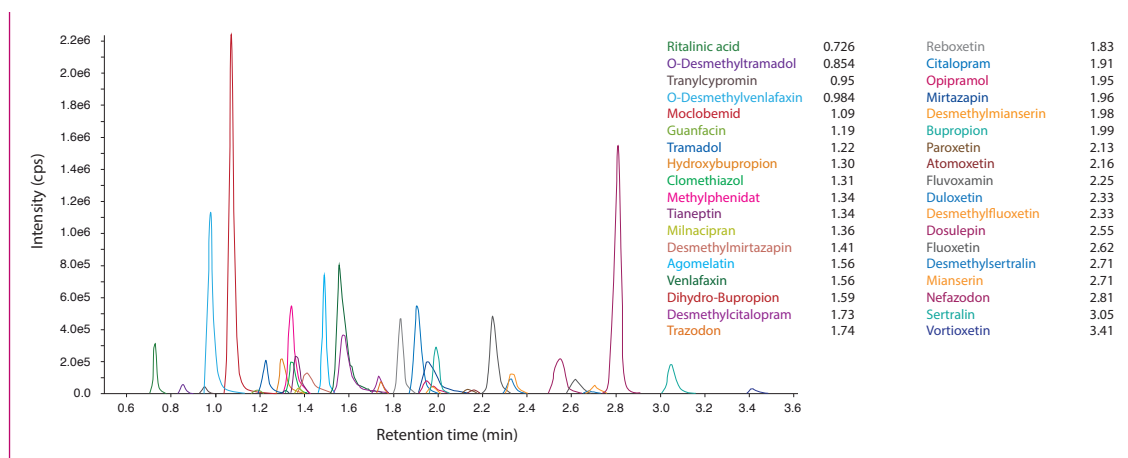
Sample Preparation



One step!

* 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 2 ml
ClinChek® Controls:		
MS9482	Serum Control, lyophil., Level I, II	2 x 5 x 1 ml

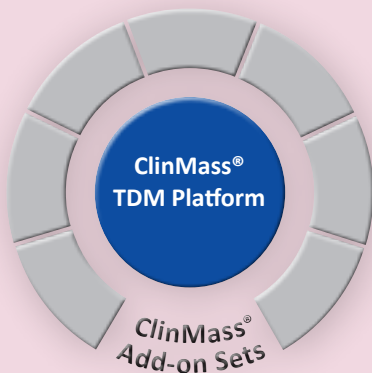
Antiepileptic Drugs in Serum / Plasma

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 26 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 µl*

* depending on the sensitivity of the mass spectrometer

Injection interval: 4.5 min

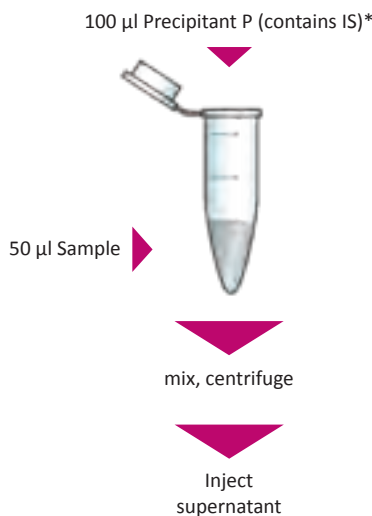
Column heater: 40 °C

MS-Parameters

Ion source: ESI, positive / negative

MS/MS mode: MRM

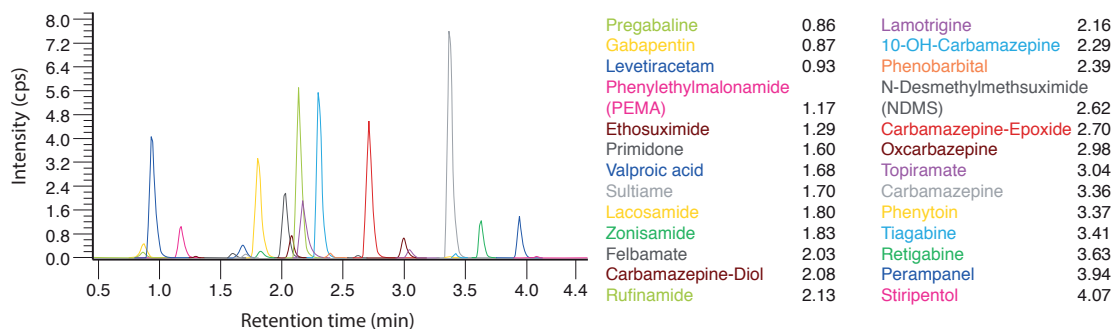
Sample Preparation



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)



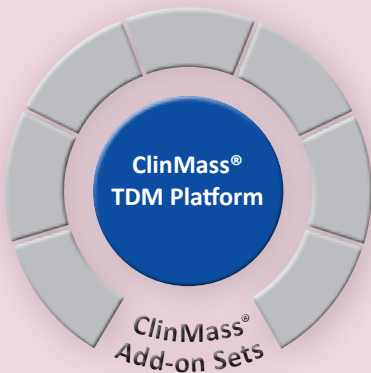
Ordering Information

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 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 immuno-compromised 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 für Antimycotics (order no. MS9600) contains all analyte specific components required for the determination of 11 drugs and metabolites. Additionally, the determination of the active metabolite Voriconazole-N-Oxide is possible as well.

- Covers 11 antimycotics
- Includes Amphotericin B, Anidulafungin, Micafungin & Isavuconazole
- Isotopically labeled Internal Standards



Test Data

Test data are available on request.

LC-MS/MS Parameters

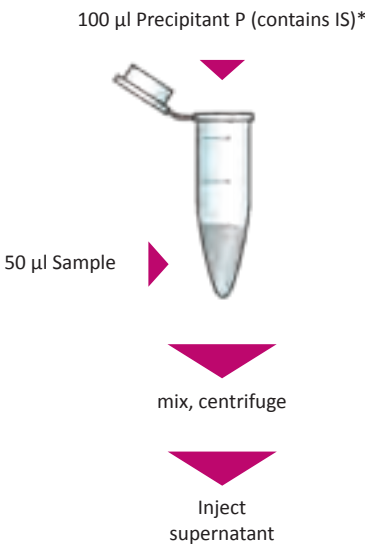
LC-Parameters

Binary Gradient	
Pump:	Mobile Phases A/B (0.6 ml/min)
Injection volume:	1 – 10 µl
Injection interval:	3.5 min
Column heater:	40 °C

MS-Parameters

Ion source:	ESI
MS/MS mode:	MRM

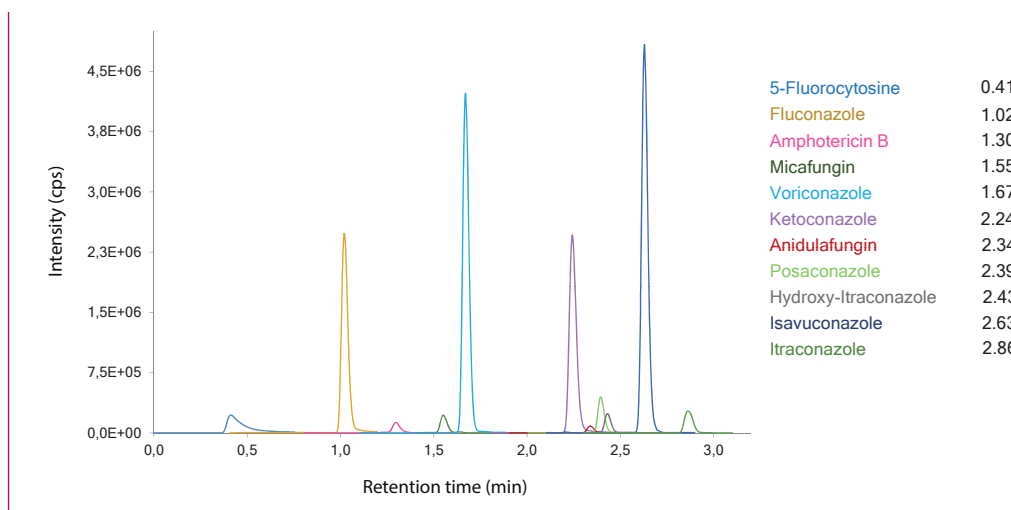
Sample Preparation



One step!

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

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



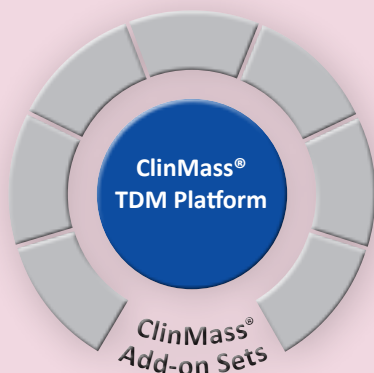
Ordering Information

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. MS9100):		
MS9612	Internal Standard IS, lyophil.	5 x 5 ml
MS9613	Serum Calibrator Set, lyophil. (Level 0 - 3)	4 x 1 x 1 ml
	Manual	
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

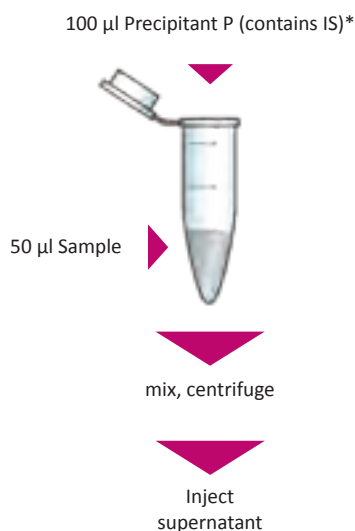
Column heater: 40 °C

MS-Parameters

Ion source: ESI, positive

MS/MS-Mode: MRM

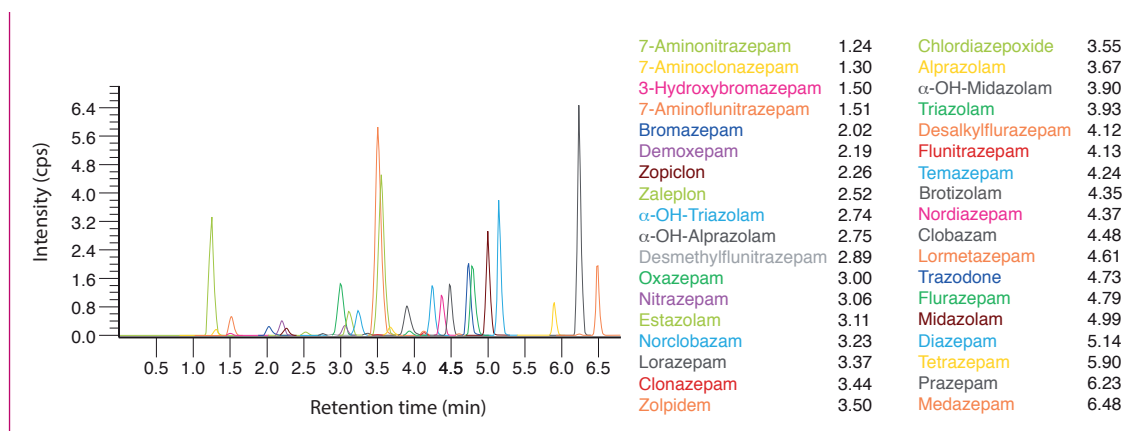
Sample Preparation



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

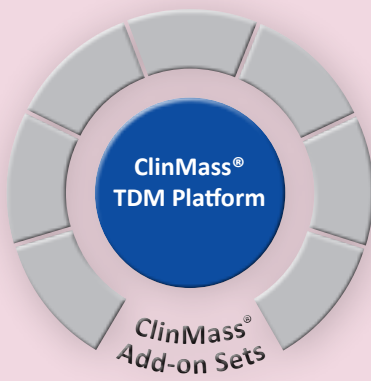
Mycophenolic Acid in Serum / Plasma

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

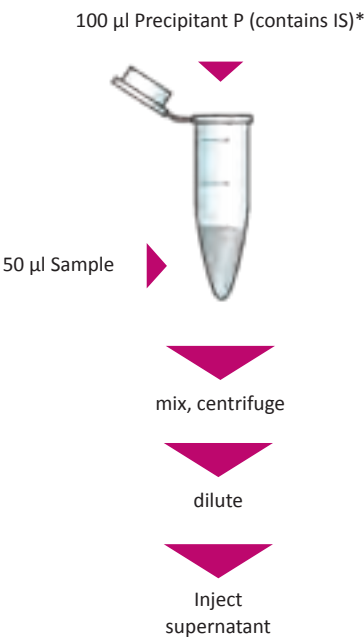
LC-Parameters

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

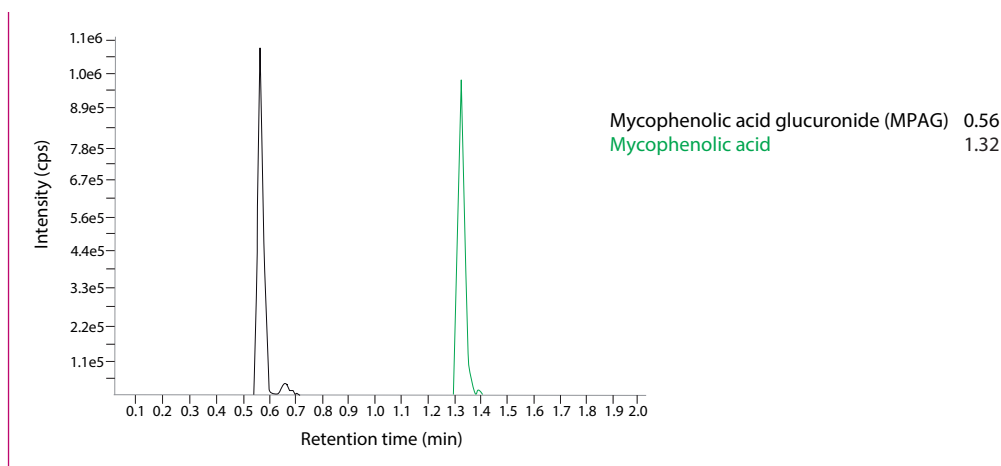
Ion source:	ESI
MS/MS mode:	MRM

Sample Preparation



* Reconstitution of IS (order no. MS9412) 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

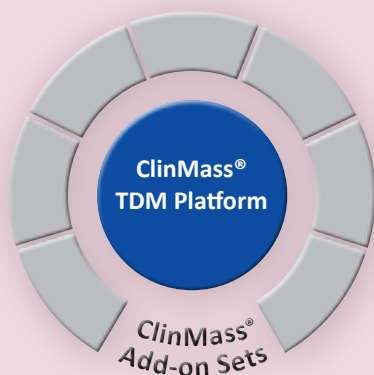
Neuroleptics in Serum/ Plasma

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 all 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 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)

Injection volume: 1 - 10 µl

Injection interval: 6.0 min

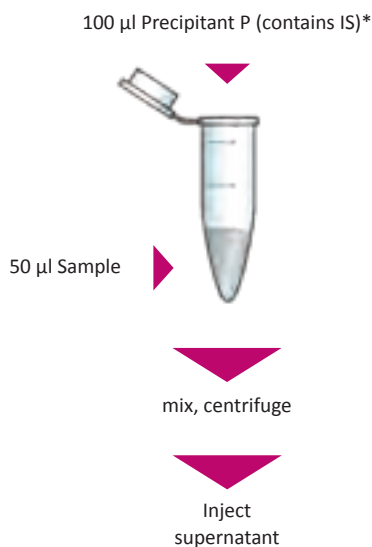
Column heater: 40 °C

MS-Parameters

Ion source: ESI

MS/MS mode: MRM

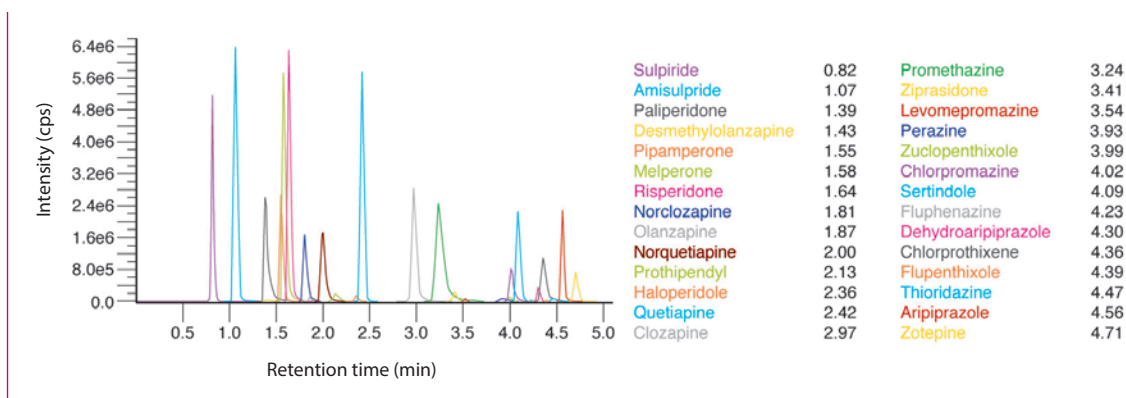
Sample Preparation



One step!

* Reconstitution of IS (order no. MS9412)
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

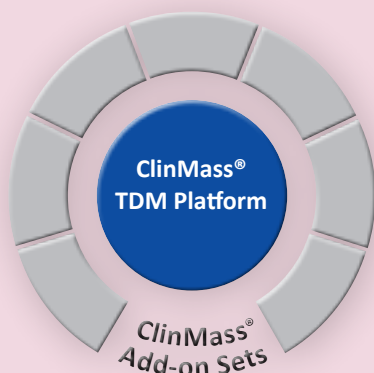
Tricyclic Antidepressants in Serum/Plasma

Tricyclic antidepressants (TCA) are a group of psychoactive drugs which are mainly used for the therapy of endogene 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

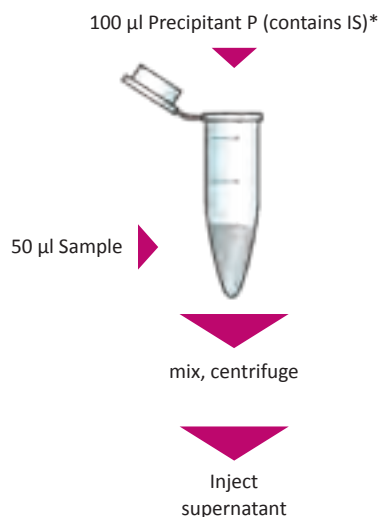
Column heater: 40 °C

MS-Parameters

Ion source: ESI, positive

MS/MS mode: MRM

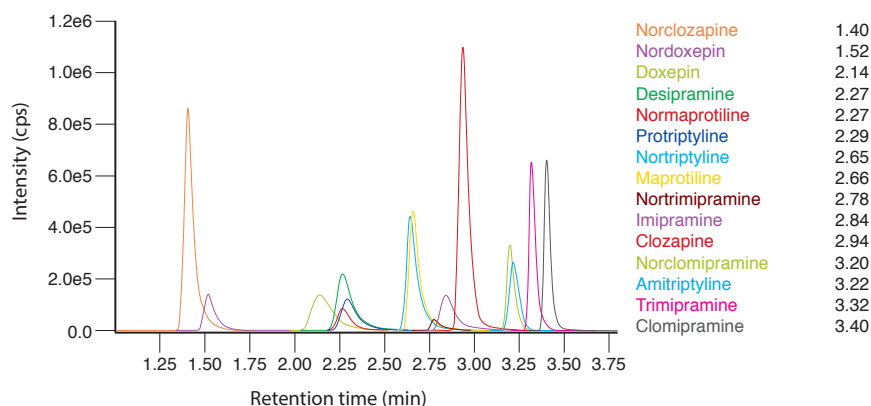
Sample Preparation



One step!

* Reconstitution of IS (order no. MS9512) 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.	2 x 2 ml
ClinChek® Controls:		
MS9182	Serum Control, lyophil., Level I, II	2 x 5 x 1 ml

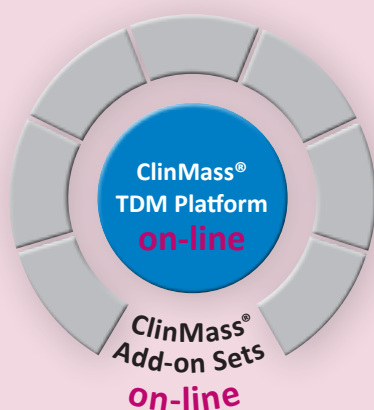
Antidepressants in Serum / Plasma

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 TeCAs.

The ClinMass® Add-on Set for Antidepressants (order no. MS9450) contains all analyte specific components required for the quantification of 37 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 (153 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

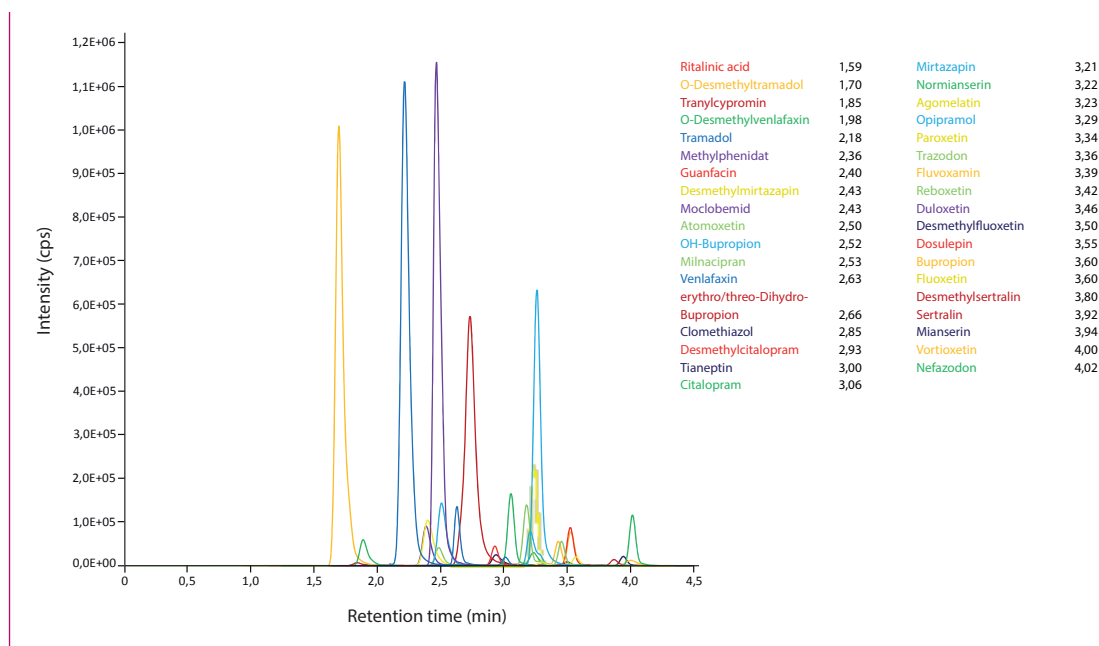
MS/MS mode: MRM

on-line SPE

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

Direct injection!

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	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	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 2 ml
ClinChek® Controls:		
MS9482	Serum Control, lyophil., Level I, II	2 x 5 x 1 ml

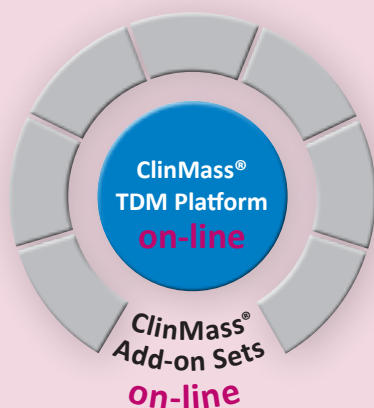
Antiepileptic Drugs in Serum / Plasma

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 27 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 (153 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

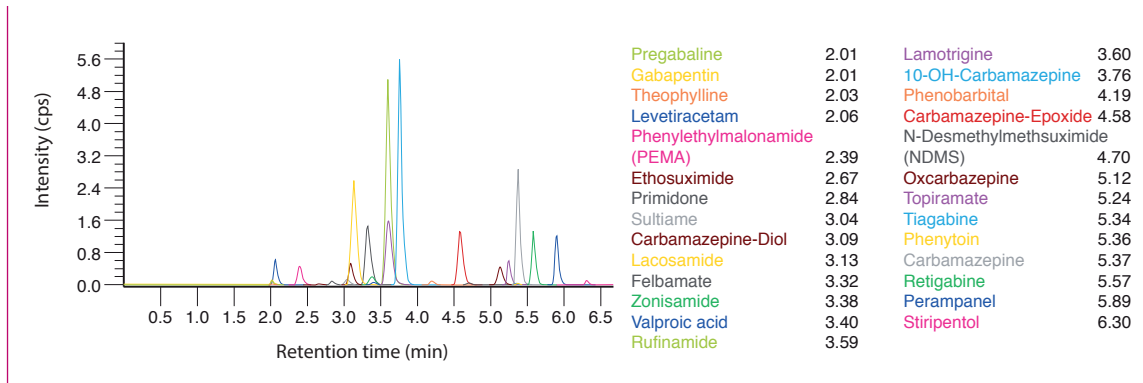
Sample Preparation

No manual sample preparation needed!

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

Direct injection!

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	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.	2 x 2 ml
ClinCheck® Controls:		
MS9282	Serum Control, lyophil., Level I, II	2 x 5 x 1 ml

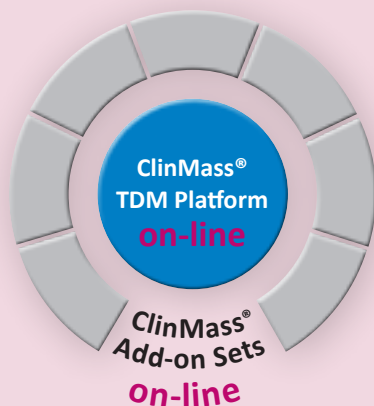
Antimycotics in Serum / Plasma

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 für Antimycotics (order no. MS9600) contains all analyte specific components required for the determination of 10 drugs and metabolites. Additionally, the determination of the active metabolite Voriconazole-N-Oxide is possible as well.

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.

- 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

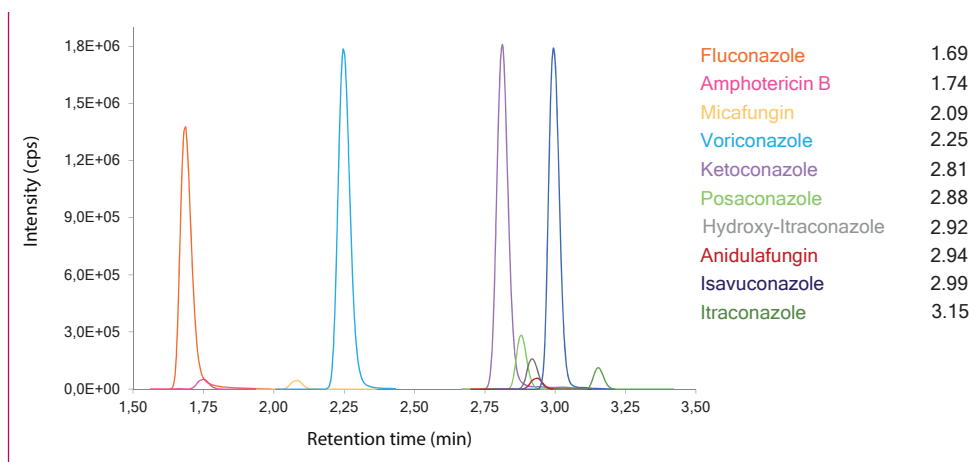
Sample Preparation

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)	4x1x1 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

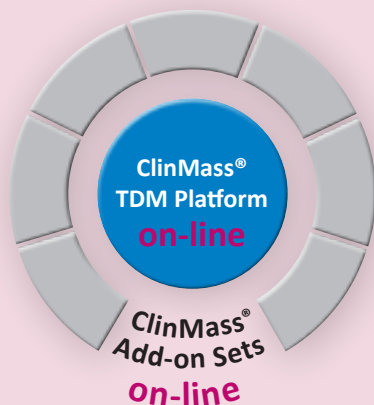
Benzodiazepines in Serum / Plasma

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 36 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 (153 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

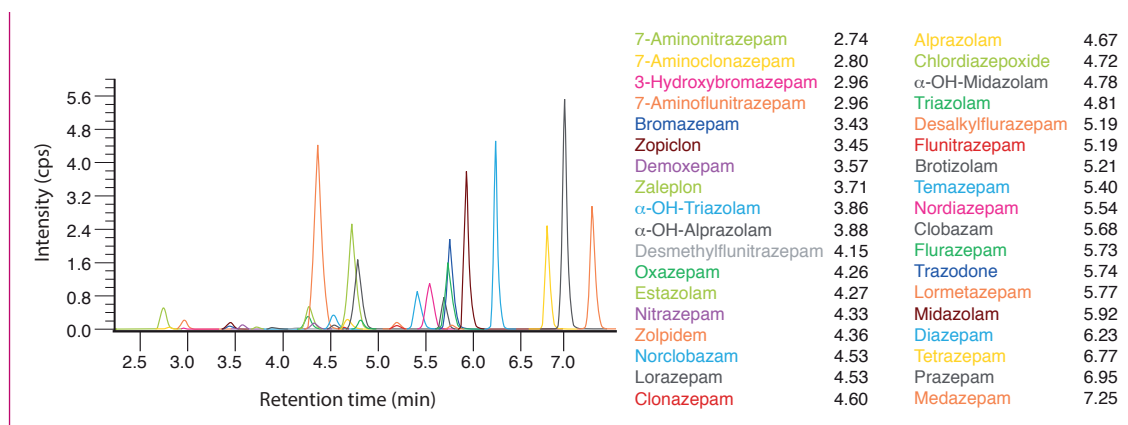
Sample Preparation

No manual sample preparation needed!

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

Direct injection!

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	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

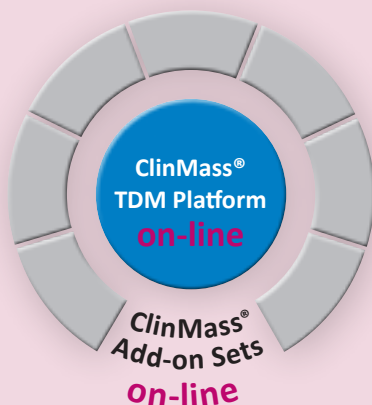
Neuroleptics in Serum / Plasma

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 (order no. MS9050) 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 (153 compounds).

- 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

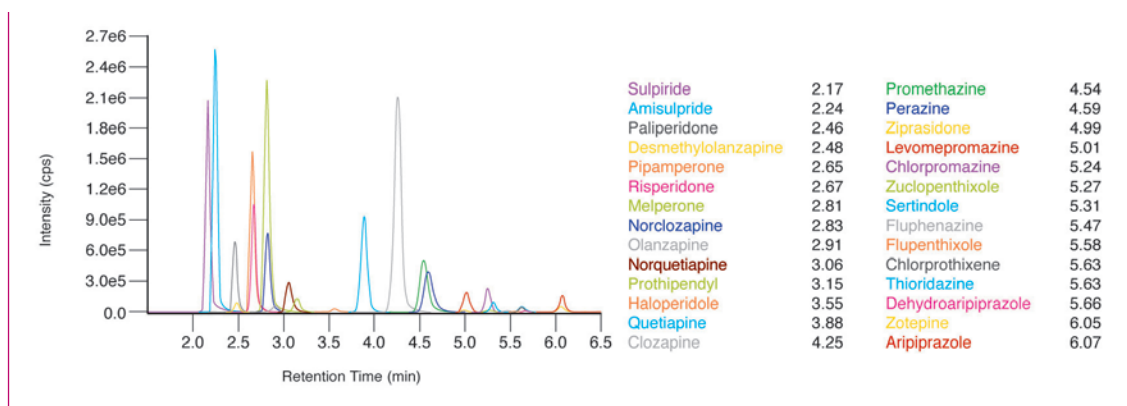
Ion source:	ESI
MS/MS mode:	MRM

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	IS Interner Standard, 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

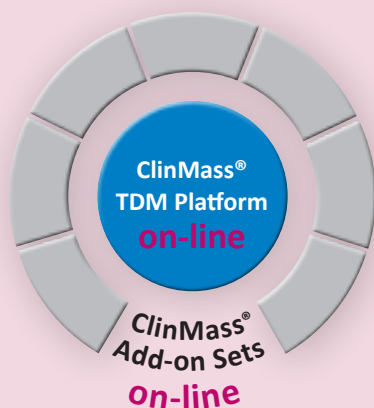
Tricyclic Antidepressants in Serum / Plasma

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 (153 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

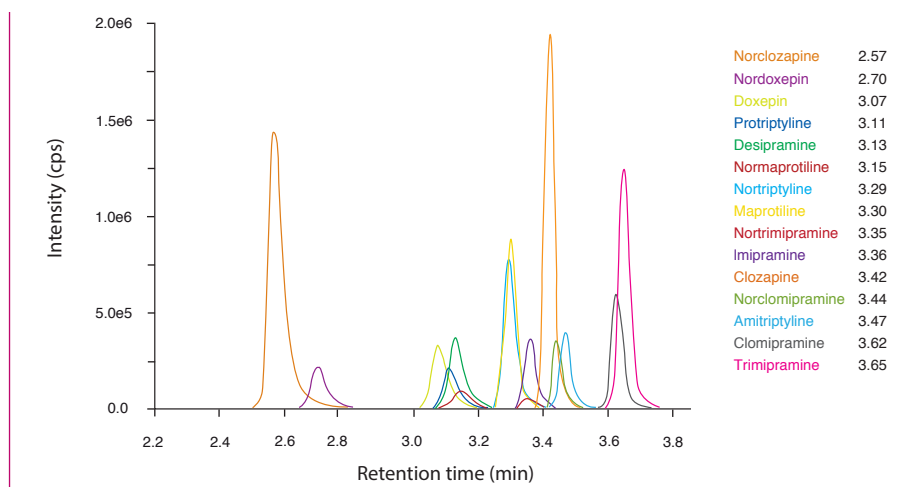
Sample Preparation

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	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.	2 x 2 ml
ClinChek® Controls:		
MS9182	Serum Control, lyophil., Level I, II	2 x 5 x 1 ml

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



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	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

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	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

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 µmol/l
LOD:	0.07 µmol/l
LLOQ:	0.2 µmol/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
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mix

Precipitation

100 µl Reagent B

1. mix
2. centrifuge

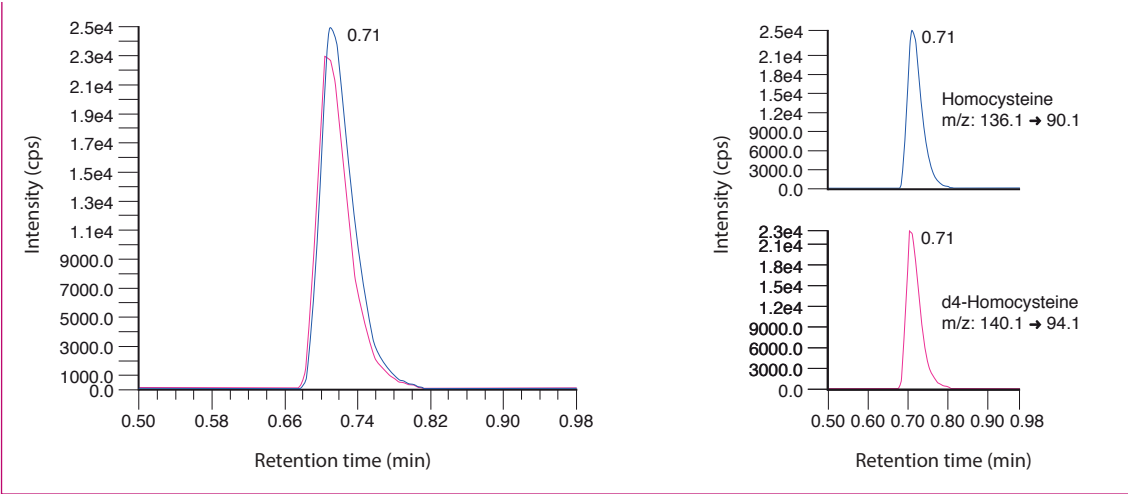
LC-MS/MS Analysis:

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,
²H₇-Citrulline, ¹³C₅-Glutamic Acid,
2-¹³C¹⁵N-Glycine, ²H₃-Leucine, ²H₃-Methionine,
²H₆-Ornithine, ¹³C₆-Phenylalanine, ¹³C₅-Proline,
¹³C₆-Tyrosine, ²H₈-Valine

Optimisation Mix Acylcarnitines

²H₉-Carnitine (²H₉-C0),
²H₃-Acetylcarnitine (²H₃-C2),
²H₃-Propionylcarnitine (²H₃-C3),
²H₃-Butyrylcarnitine (²H₃-C4),
²H₉-Isovalerylcarnitine (²H₉-C5),
²H₉-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,
Dosulepin, Fluoxetine, Mianserin, Milnacipran,
Mirtazapine, Opipramol, Reboxetine,
Sertraline, Trazodone, Venlafaxine

Optimisation Mix 2:

Clomethiazole, Desmethyfluooxetine,
Desmethylmirtazapine, Desmethylsertraline,
erythro-Dihydro-Bupropion, Duloxetine,
Fluvoxamine, Hydroxybupropion,
Moclobemide, O-Desmethylvenlafaxine,
Paroxetine, Ritalinic Acid, Tranylcypromine

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.	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.	5 x 1 x 2 ml

► Antiepileptic Drugs

Analytes:

Optimisation Mix 1:

Carbamazepine, Felbamate, Oxcarbazepine, PEMA, Rufinamide, Vigabatrine

Optimisation Mix 2:

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

Optimisation Mix 3:

Carbamazepine-Diol, Lacosamide, Levetiracetam, Pregabalin, Theophylline

Optimisation Mix 4:

Carbamazepine-Epoxide, 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

4.1 ClinMass® Optimisation Mixes

► Benzodiazepines

Analytes:

Optimisation Mix 1:

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

Optimisation Mix 2:

Bromazepam, Clobazam, Lormetazepam, Nitrazepam, Norclobazam, Nordiazepam

Optimisation Mix 3:

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

Optimisation Mix 4:

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

Optimisation Mix 5:

alpha-Hydroxytriazolam, 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, 13Cd2d4-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

► Metanephrynes

Analytes:

Optimisation Mix:

3-Methoxytyramine, d4-3-Methoxytyramine, Metanephryne, d3-Metanephryne, Normetanephryne, d3-Normetanephryne

Order No.	Description	Quantity
MS11014	ClinMass® Optimisation Mix for Metanephrynes	2 ml

4.1 ClinMass® Optimisation Mixes

► Methylmalonic Acid

Analytes:

Optimisation Mix:

Methylmalonic Acid, d3-Methylmalonic Acid

► Mycophenolic Acid

Analytes:

Optimisation Mix:

Mycophenolic Acid

► 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)

► Steroids

Analytes:

Optimisation Mix 1:

Androstenedione, 11-Deoxycortisol, 17-Hydroxyprogesterone, DHEAS

Optimisation Mix 2:

Cortisol, 21-Deoxycortisol, 21-Hydroxyprogesterone, Testosterone

► 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
MS5114	ClinMass® Optimisation Mix for Methylmalonic	2 ml

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

Order No.	Description	Quantity
MS9314	ClinMass® Optimisation Mix for Neuroleptics, lyophil.	2 x 1 x 2 ml

Order No.	Description	Quantity
MS12014	ClinMass® Optimisation Mix for Steroids	2 x 1 x 2 ml

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

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, ²H₇-Citrulline, ¹³C₅-Glutamic Acid, ²⁻¹³C¹⁵N-Glycine, ²H₃-Leucine, ²H₃-Methionine, ²H₆-Ornithine, ¹³C₆-Phenylalanine, ¹³C₅-Proline, ¹³C₆-Tyrosine, ²H₈-Valine

Acylcarnitines

²H₉-Carnitine (²H₉-C0), ²H₃-Acetylcarnitine (²H₃-C2), ²H₃-Propionylcarnitine (²H₃-C3), ²H₃-Butyrylcarnitine (²H₃-C4), ²H₉-Isovalerylcarnitine (²H₉-C5), ²H₉-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
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, d₃-Atomoxetine, d₉-Bupropion, d₆-Citalopram, d₃-Desmethylycitalopram, d₅-Desmethylyfluoxetine, 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-Opipramol, 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

► 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

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

► Antiepileptic Drugs

Analytes:

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

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

► Antimycotics

Analytes:

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

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

► Benzodiazepines

Analytes:

d₄-7-Aminoclonazepam, d₇-7-Aminoflunitrazepam, d₅-a-Hydroxylprazolam, 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:

d₅-Ethylglucuronide, d₅-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:

d₈-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

d₁₂-Cyclosporin A, ¹³Cd₂-Tacrolimus,
¹³Cd₃-Sirolimus, ¹³C₂d₄-Everolimus

d₁₂-Cyclosporin A, ¹³Cd₂-Tacrolimus,
¹³Cd₃-Sirolimus, ¹³C₂d₄-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:

d₃-Metanephrine, d₄-3-methoxytyramine,
d₃-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:

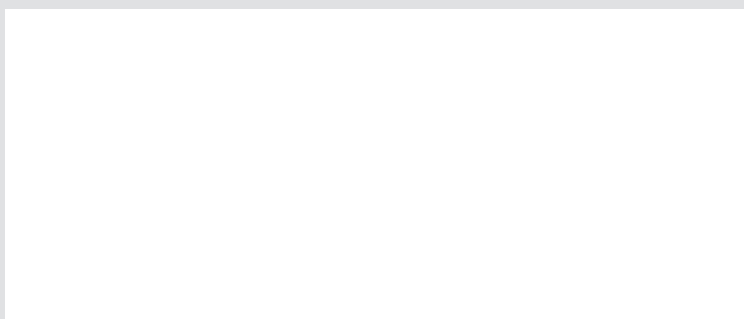
d₆-25-OH-Vitamin D3

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