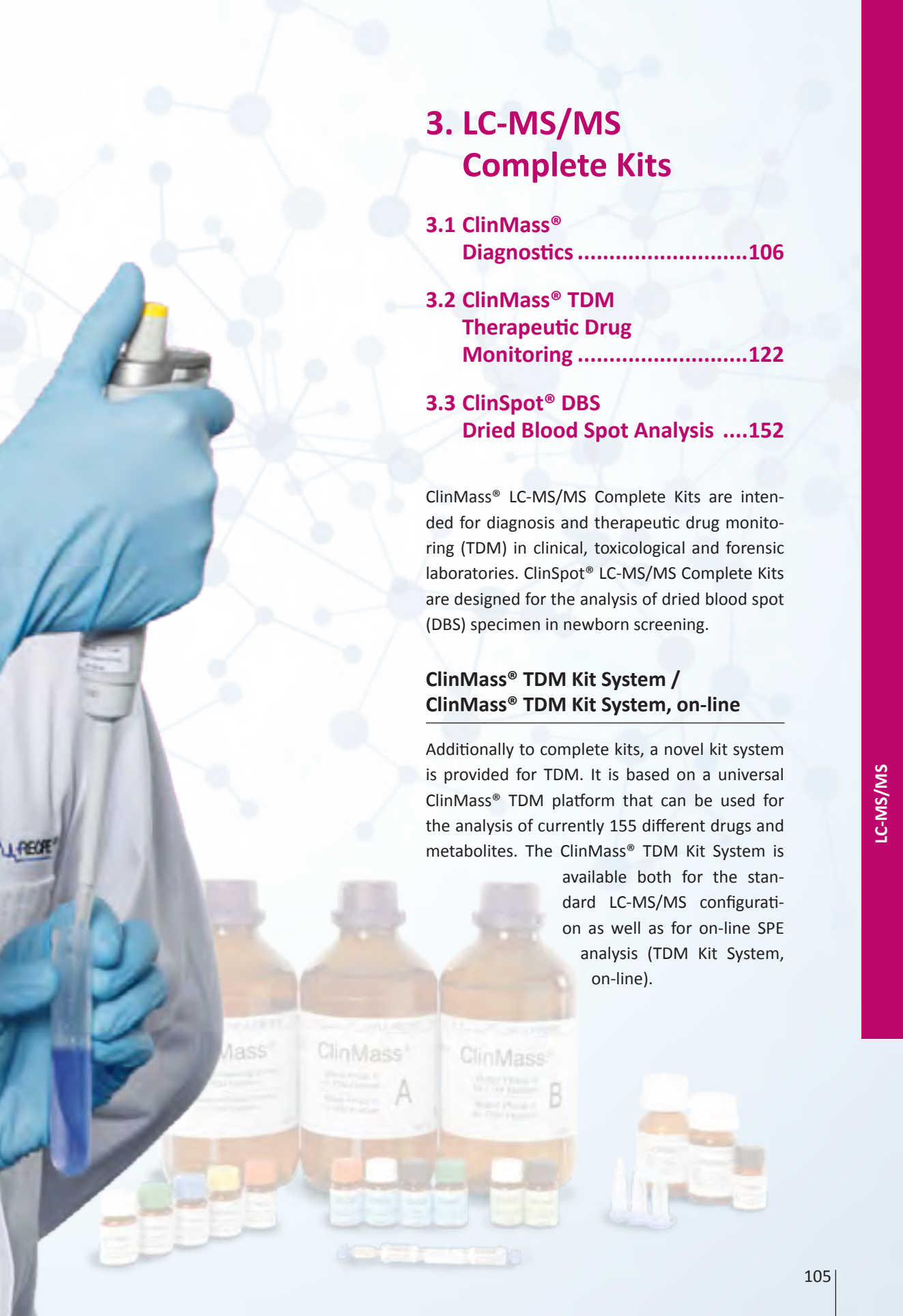




3. LC-MS/MS Complete Kits

**3.1 ClinMass®
Diagnostics106**

**3.2 ClinMass® TDM
Therapeutic Drug
Monitoring122**

**3.3 ClinSpot® DBS
Dried Blood Spot Analysis152**

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

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

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

Ethylglucuronide and Ethylsulfate in Urine, Plasma and Serum

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

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



Test Data (Urine)

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

LC-MS/MS Parameters

LC-Parameters

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

MS-Parameters

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

Sample Preparation

A: Urine

Dilution / Dotation with IS:

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

LC-MS/MS Analysis:

Inject 10 µl

B: Plasma / Serum

Precipitation / Dotation with IS:

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

mix, centrifuge

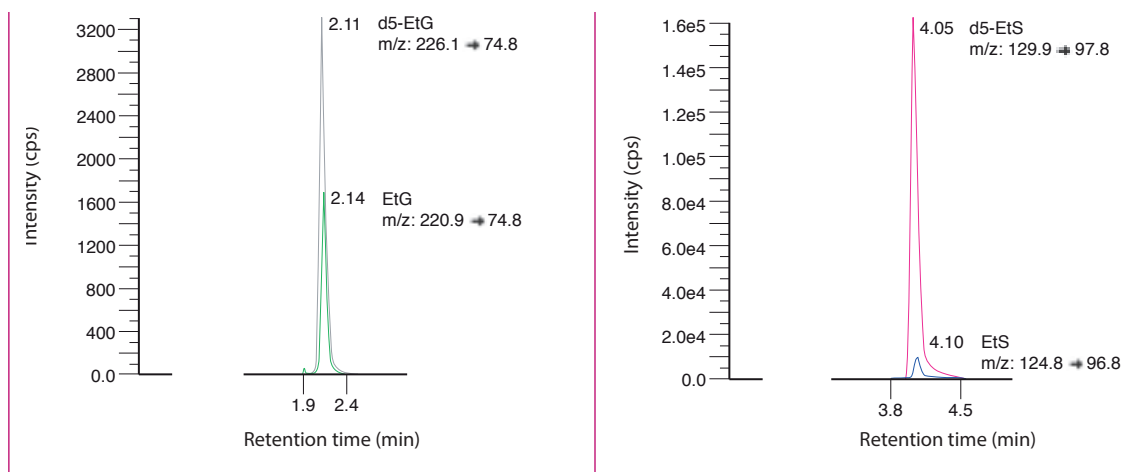
Dilution:

50 µl supernatant	500 µl Diluting Solution D
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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

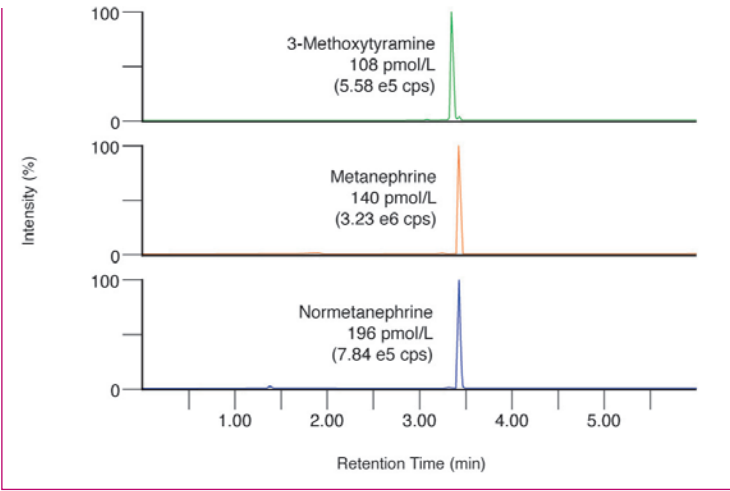
collect the eluate

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

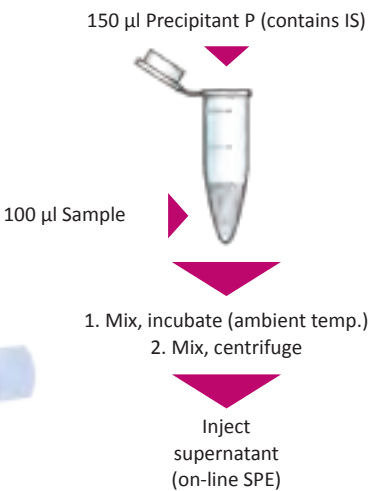
LC-Parameters

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

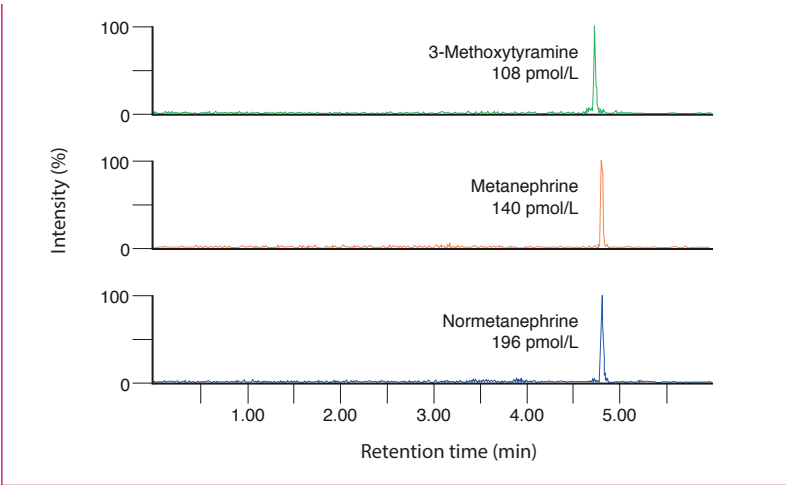
MS-Parameters

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:

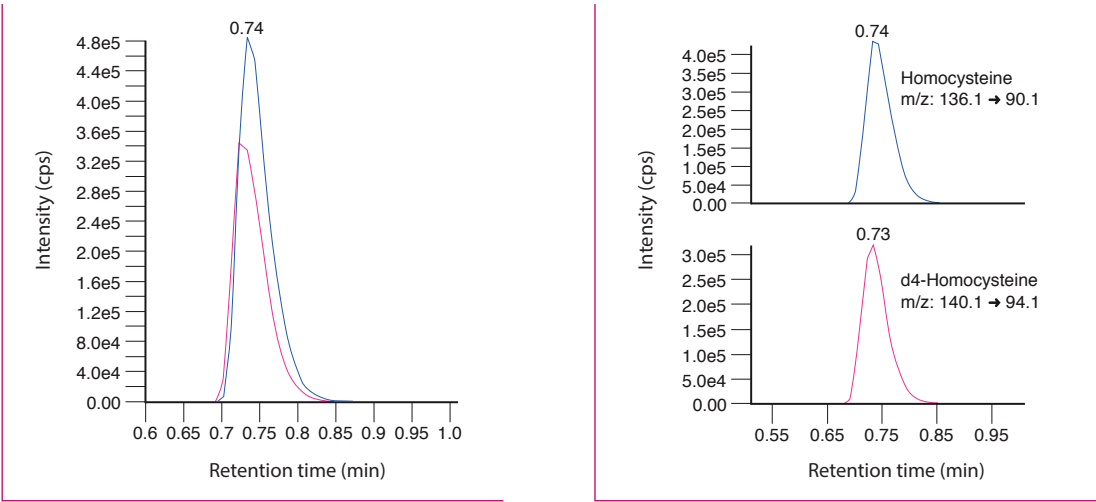
200 µl Reagent B

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:

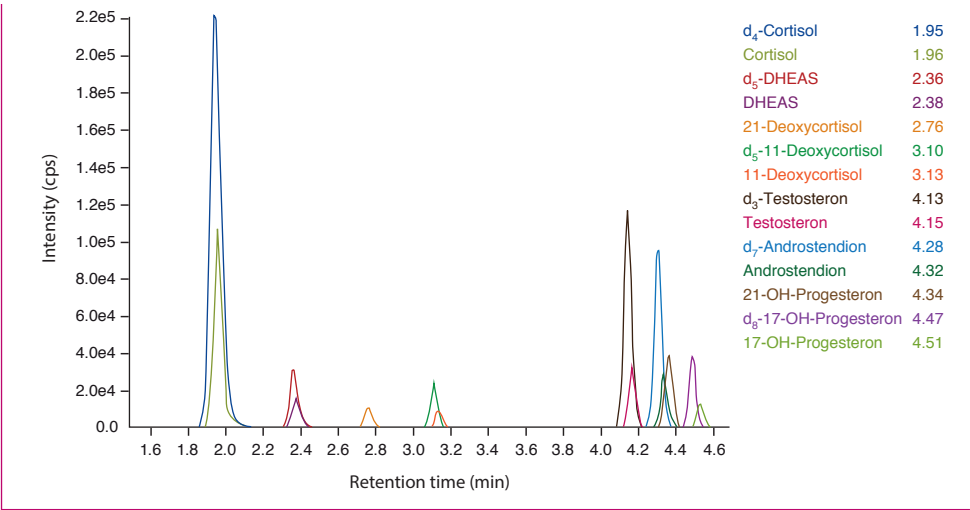
75 µl Mixture IS/ P	50 µl sample (calibrator, control, patient)
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1. mix, precipitate
2. mix, centrifuge

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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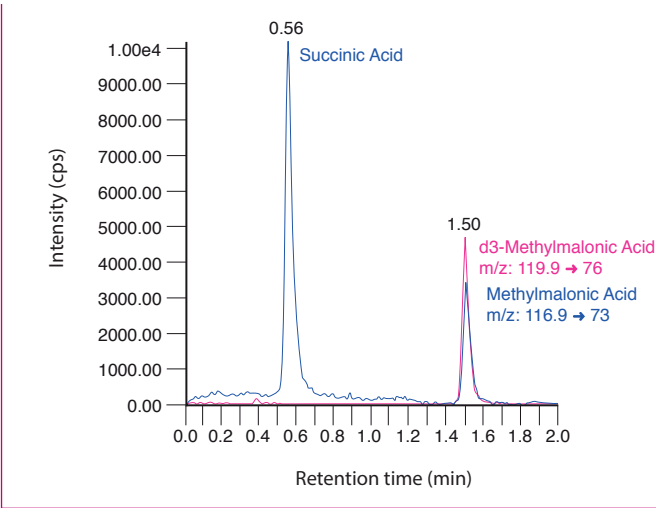
mix and centrifuge

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

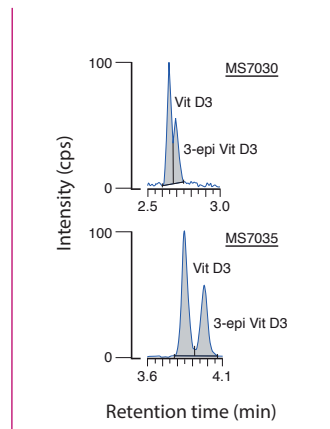
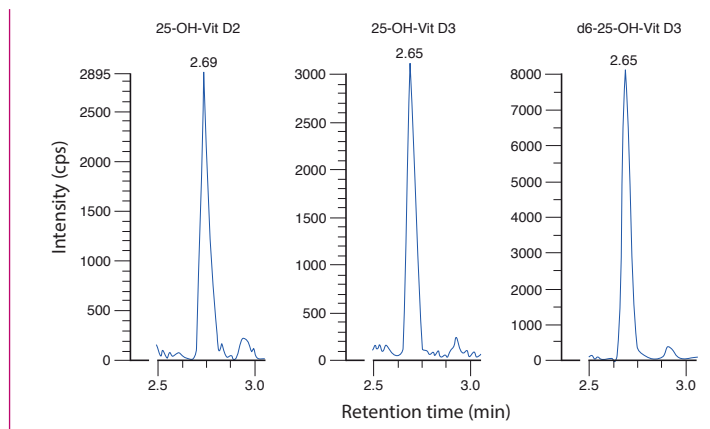


on-line Analysis:

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)
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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



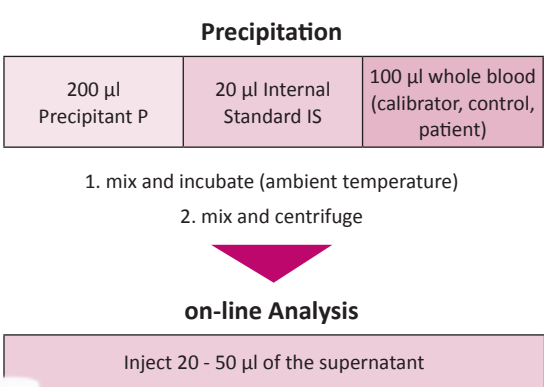
Test Data

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)

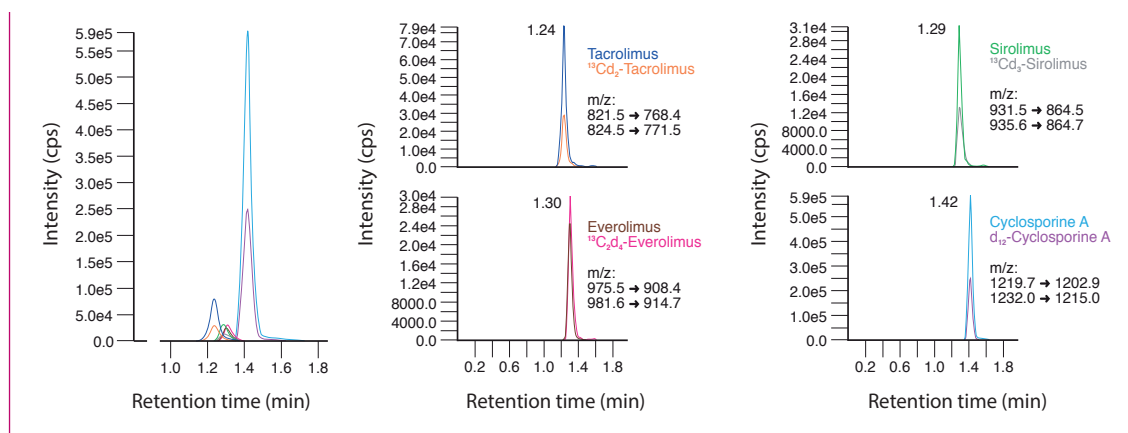
LC-MS/MS Parameters

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

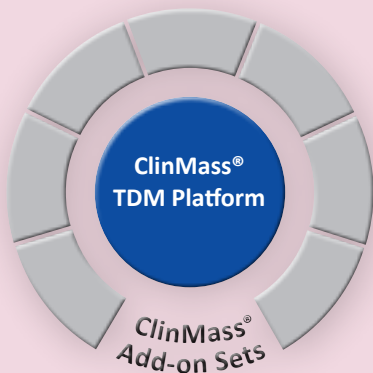
Ordering Information

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

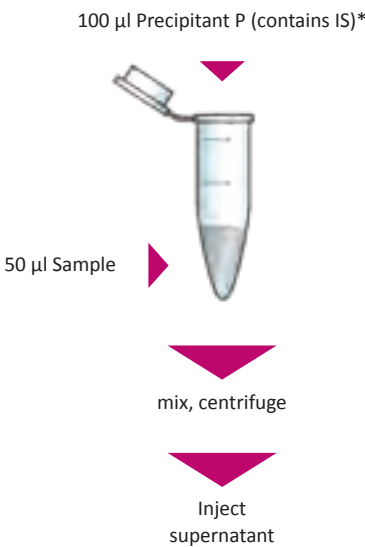
Column heater: 40 °C

MS-Parameters

Ion source: ESI, positive

MS/MS mode: MRM

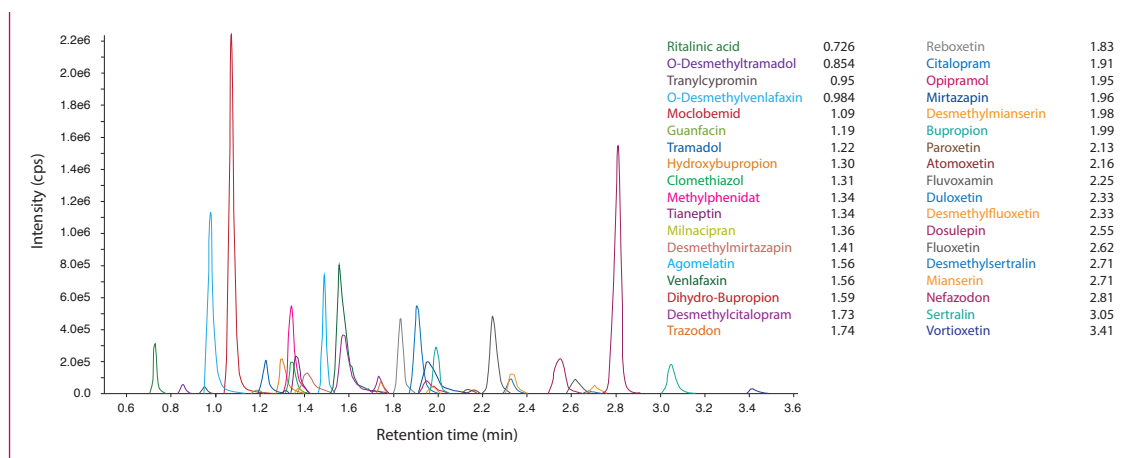
Sample Preparation



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

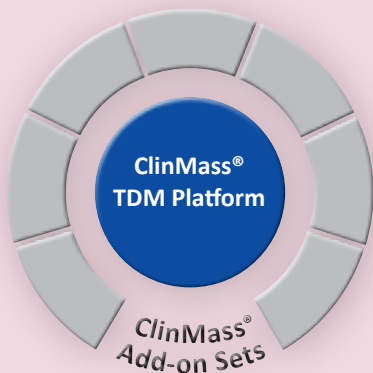
Antiepileptic Drugs in Serum / Plasma

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

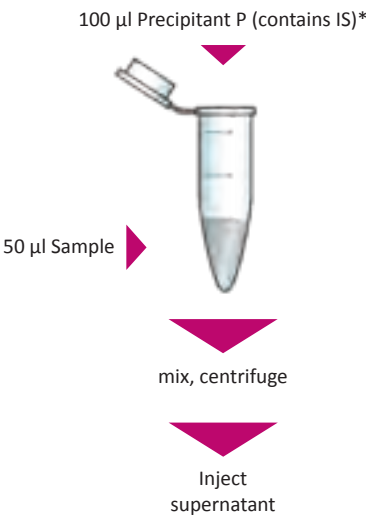
Column heater: 40 °C

MS-Parameters

Ion source: ESI, positive / negative

MS/MS mode: MRM

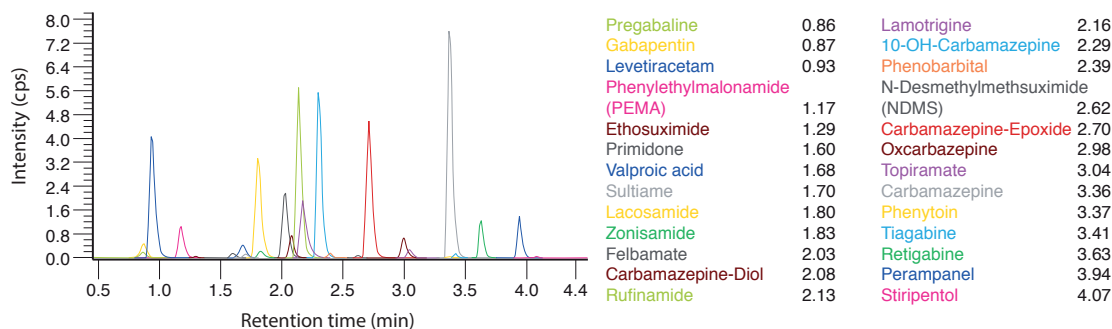
Sample Preparation



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)



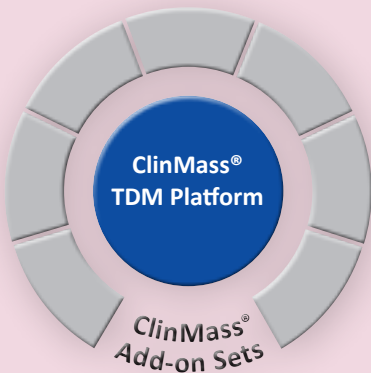
Ordering Information

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

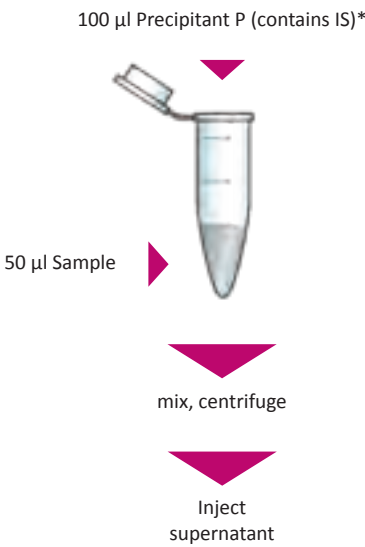
LC-Parameters

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

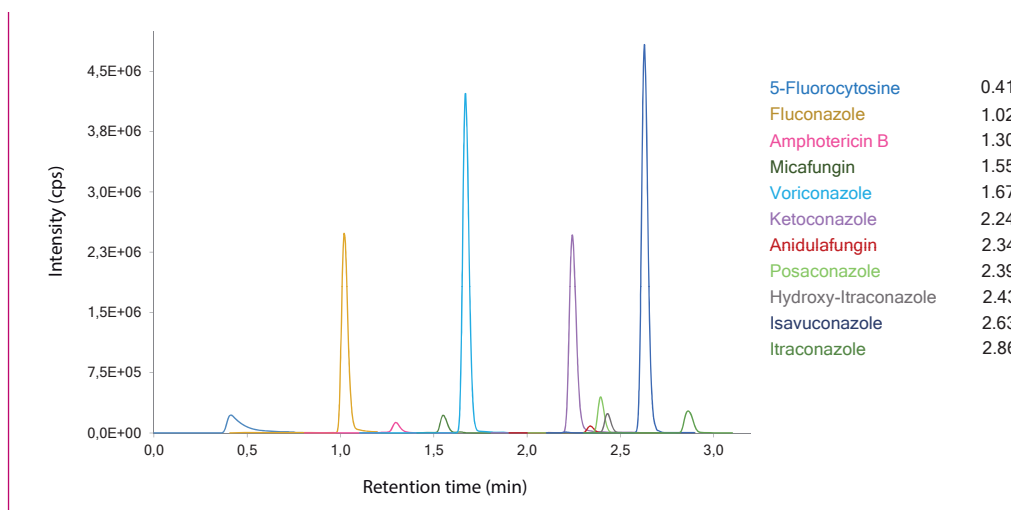
Sample Preparation



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)



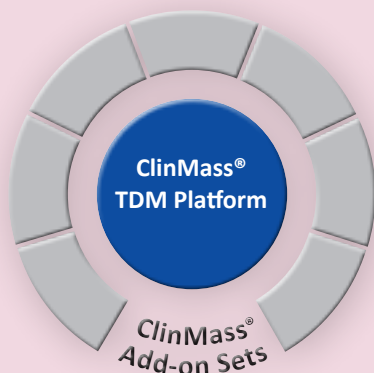
Ordering Information

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

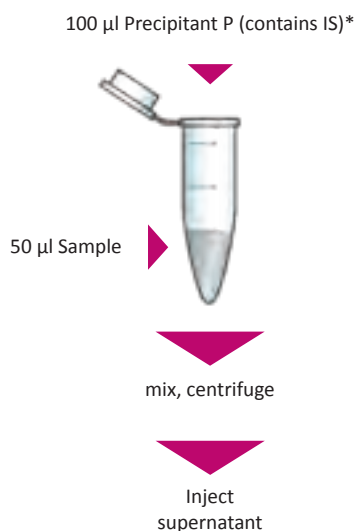
Column heater: 40 °C

MS-Parameters

Ion source: ESI, positive

MS/MS-Mode: MRM

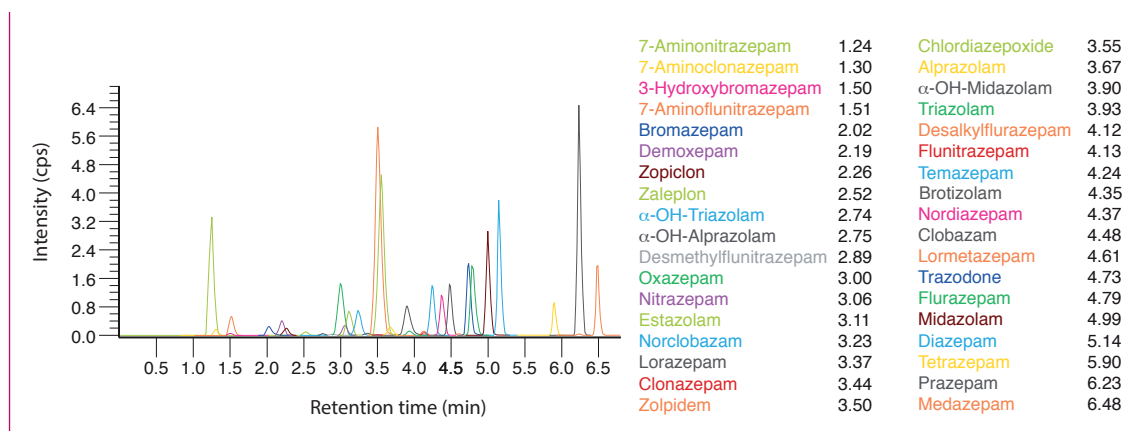
Sample Preparation



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

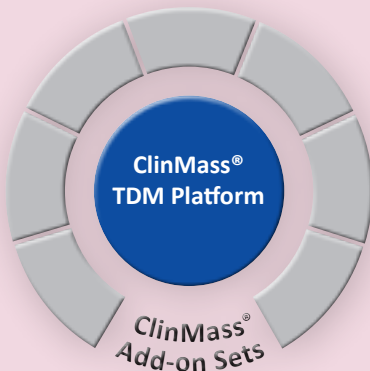
Mycophenolic Acid in Serum / Plasma

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

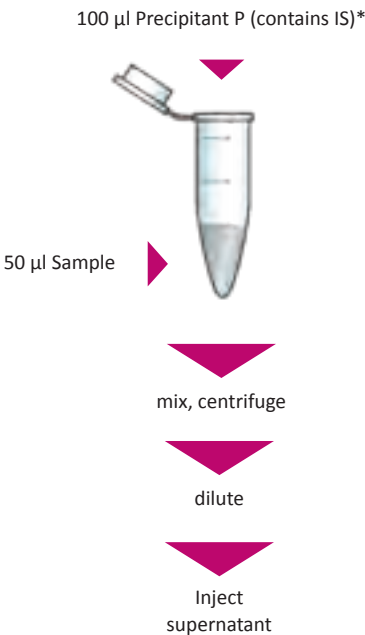
Column heater: 40 °C

MS-Parameters

Ion source: ESI

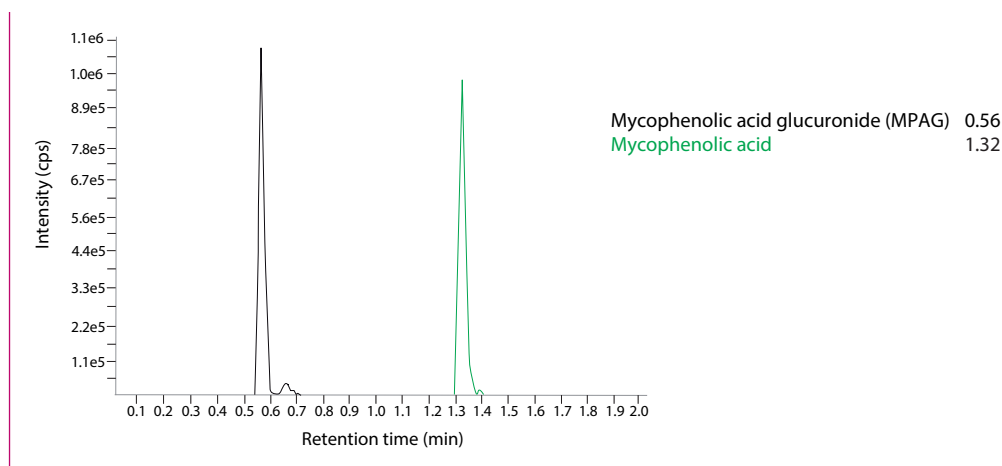
MS/MS mode: MRM

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

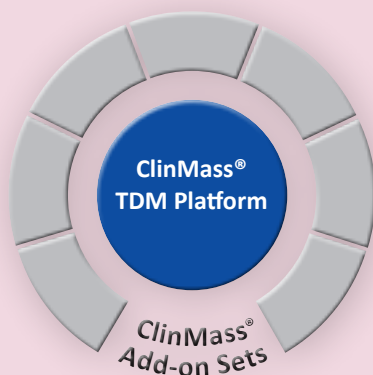
Neuroleptics in Serum/ Plasma

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

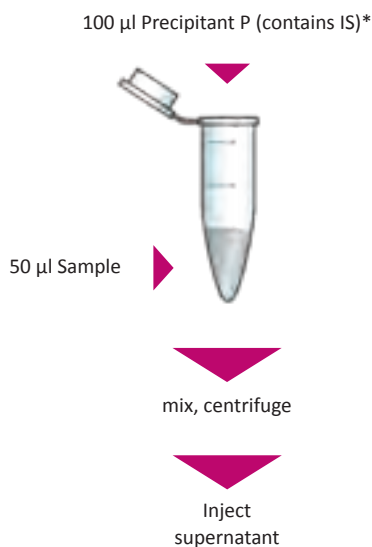
Column heater: 40 °C

MS-Parameters

Ion source: ESI

MS/MS mode: MRM

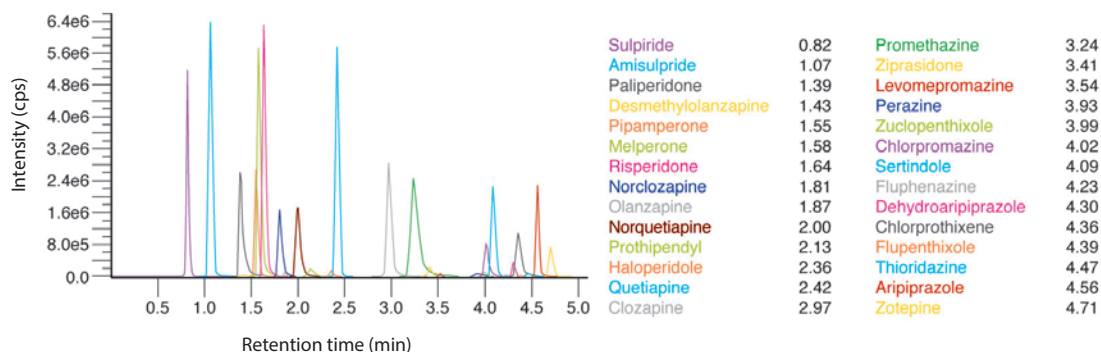
Sample Preparation



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

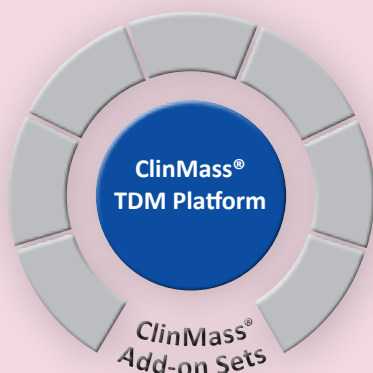
Tricyclic Antidepressants in Serum/Plasma

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

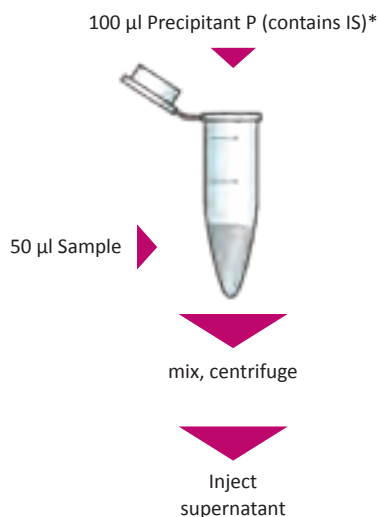
Column heater: 40 °C

MS-Parameters

Ion source: ESI, positive

MS/MS mode: MRM

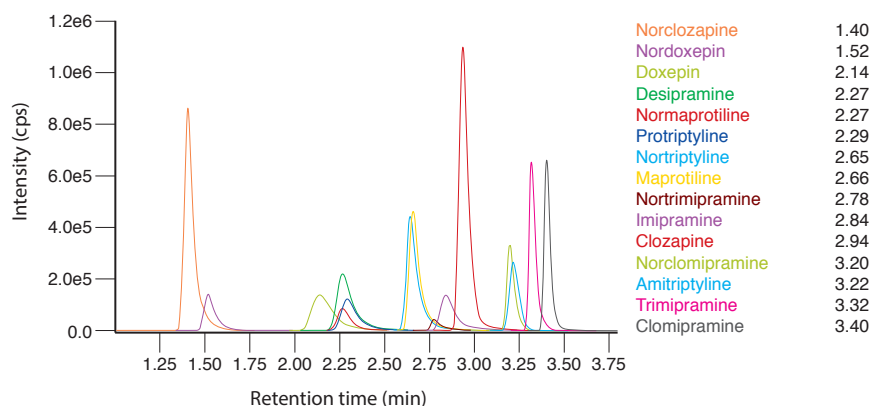
Sample Preparation



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

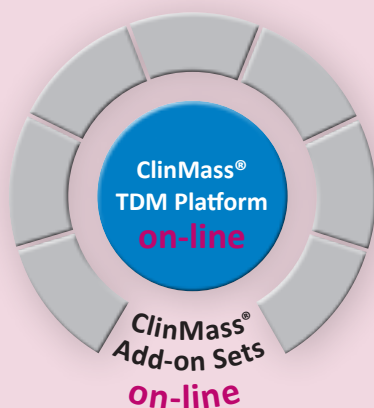
Antidepressants in Serum / Plasma

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

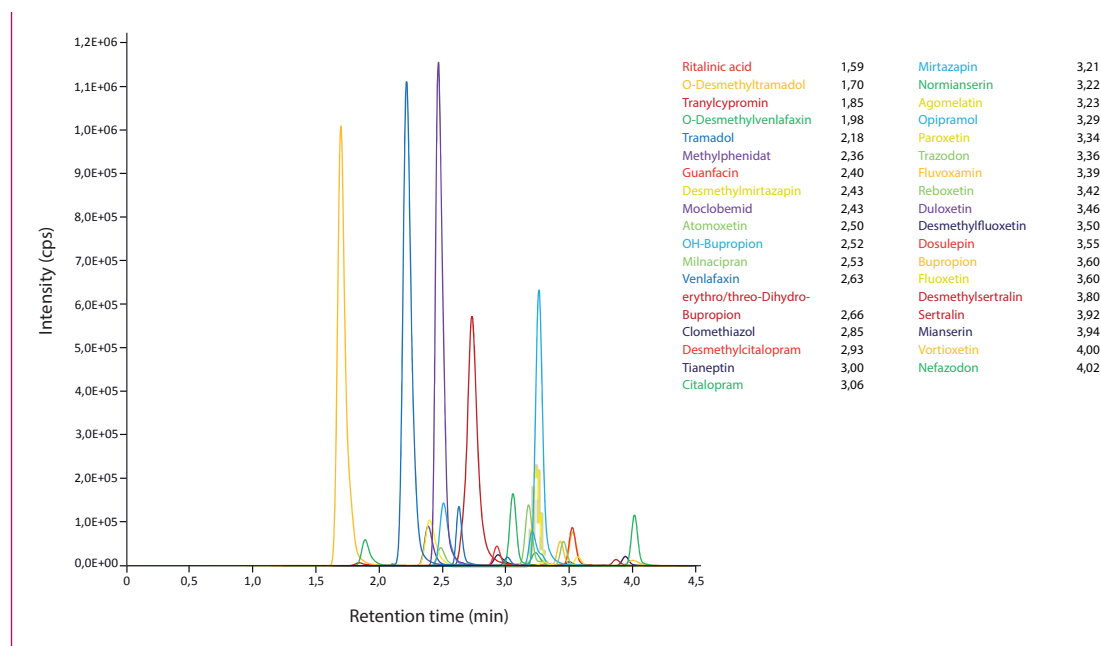
MS/MS mode: MRM

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

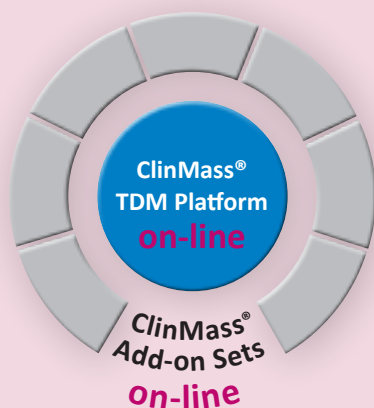
Antiepileptic Drugs in Serum / Plasma

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

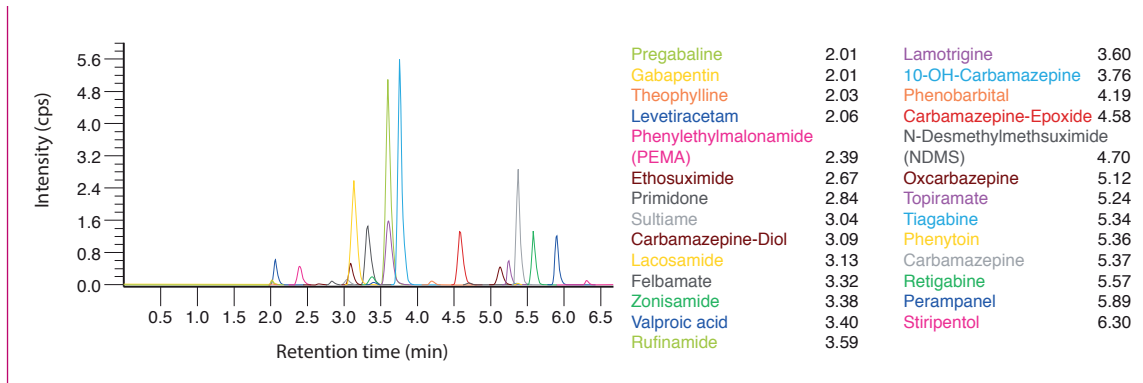
Sample Preparation

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

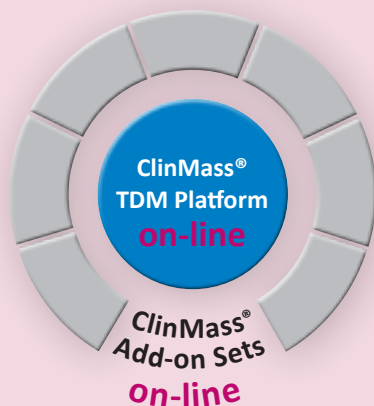
Antimycotics in Serum / Plasma

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

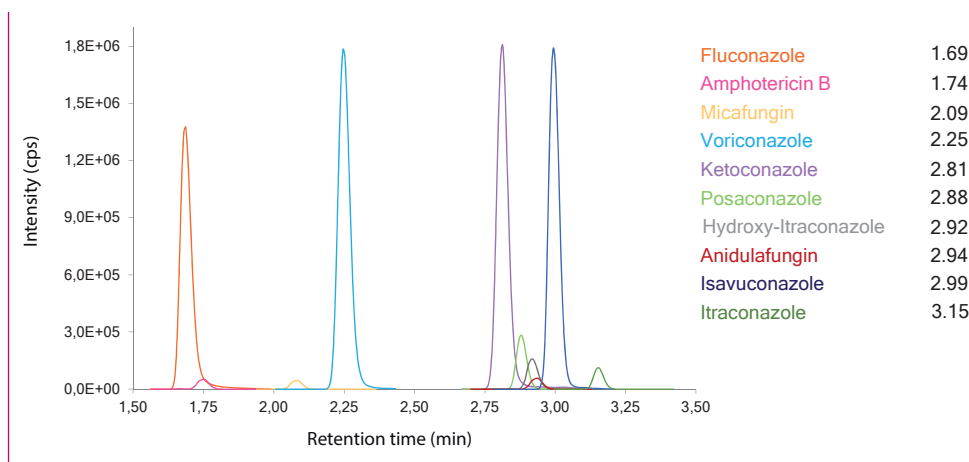
Sample Preparation

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

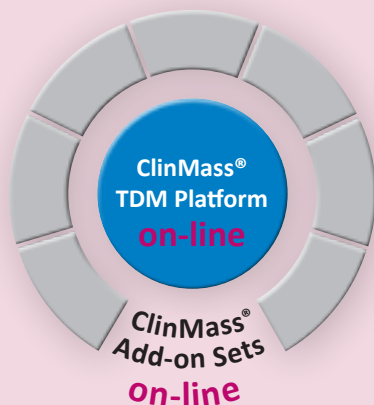
Benzodiazepines in Serum / Plasma

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

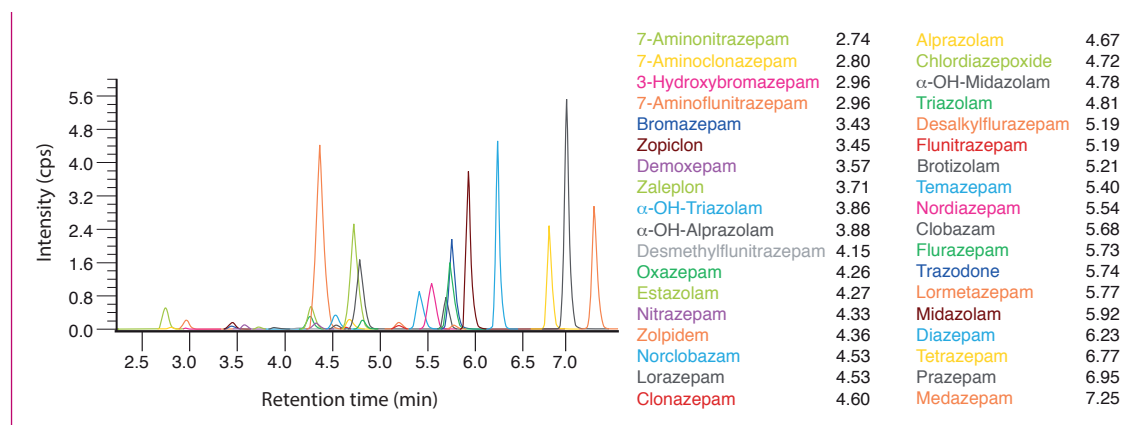
Sample Preparation

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

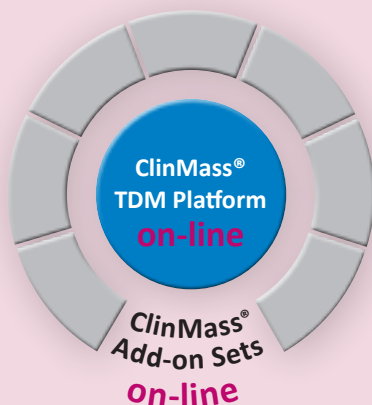
Neuroleptics in Serum / Plasma

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

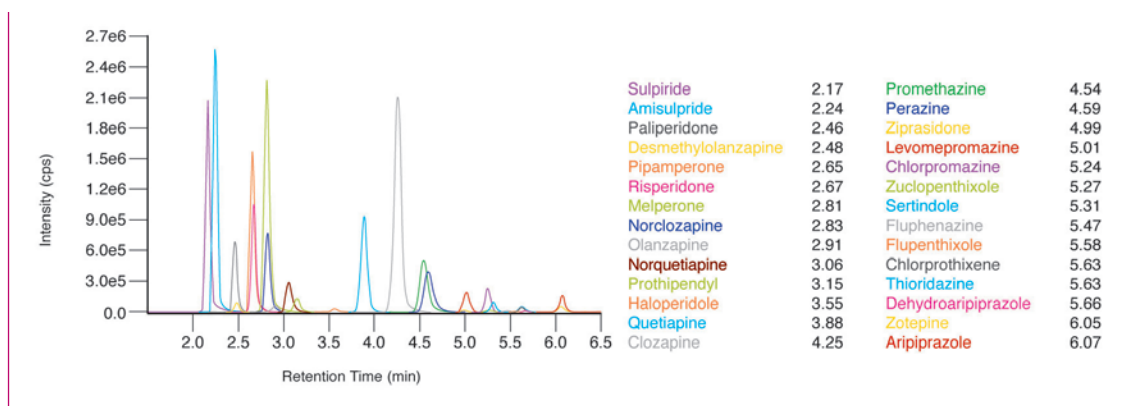
Ion source:	ESI
MS/MS mode:	MRM

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

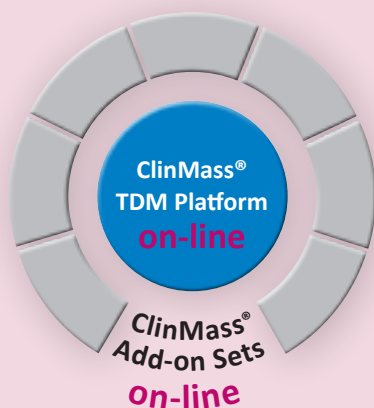
Tricyclic Antidepressants in Serum / Plasma

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

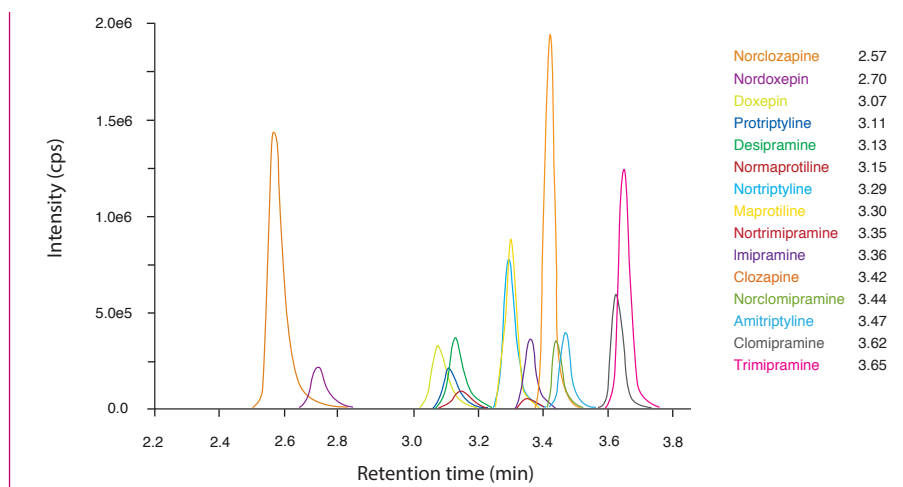
Sample Preparation

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
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extract



Transfer:

Transfer supernatant into well-plate 2
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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
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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

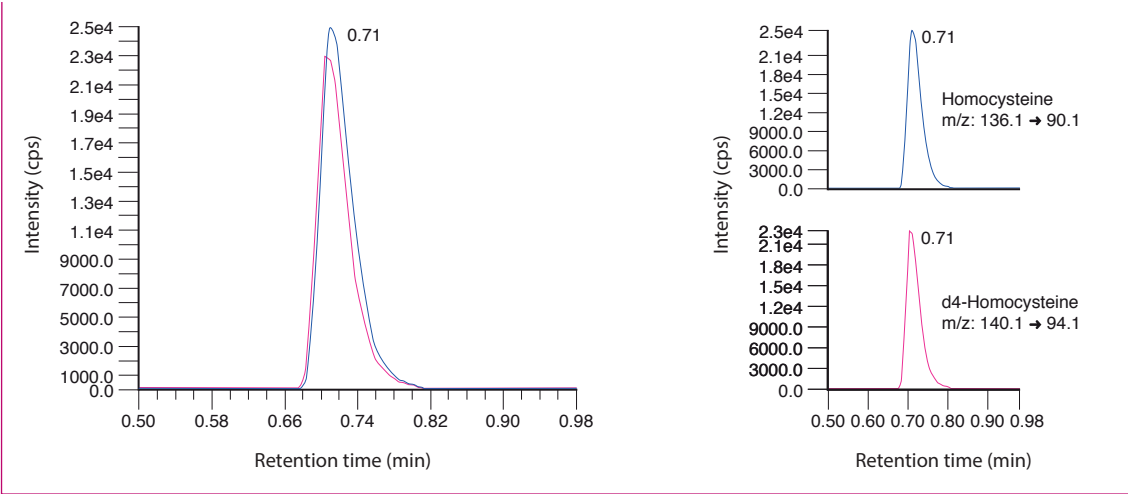
LC-MS/MS Analysis:

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