

1. HPLC

Complete Kits

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

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



CDT in Serum

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

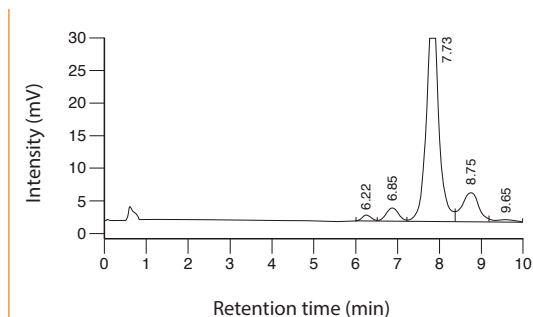
100 µl supernatant	1.0 ml Diluting Solution D
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HPLC Analysis:

Inject 400 - 500 µl

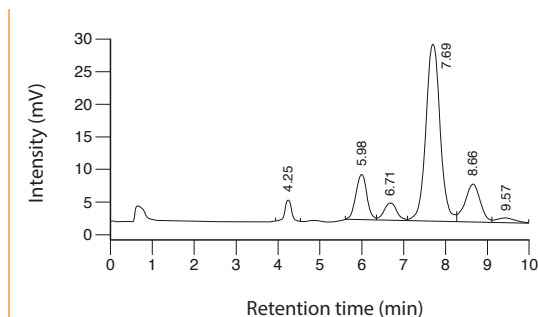
1.1.1. Alcoholism

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

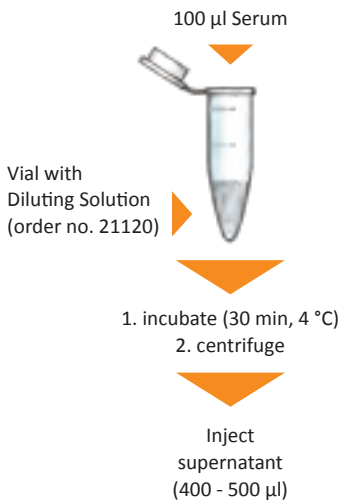
LOD:	0.1 %*
LLOQ:	0.3 %*
Intraassay precision:	4.5 %
Interassay precision:	3.9 %

* 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

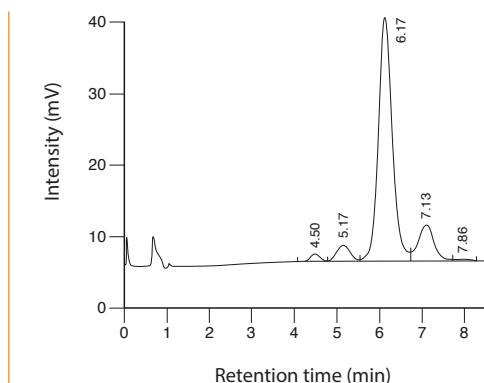
Sample Pretreatment



**One step
sample pretreatment!**

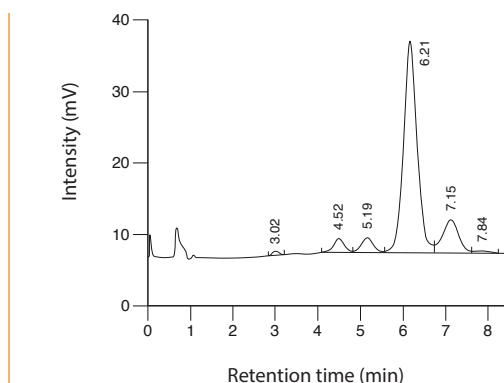
1.1.1. Alcoholism

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

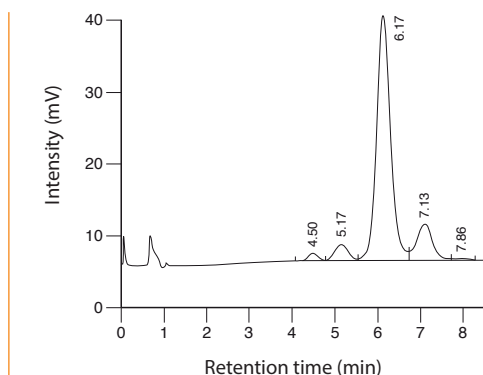


on-line Analysis:

Inject 400 µl

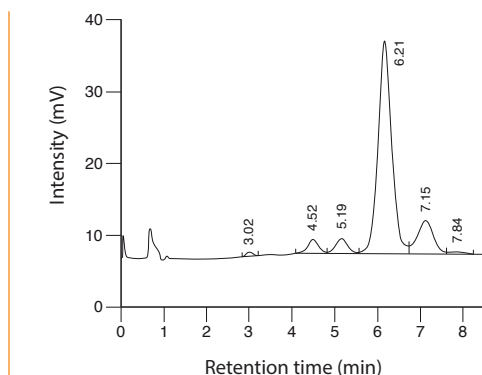
1.1.1. Alcoholism

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

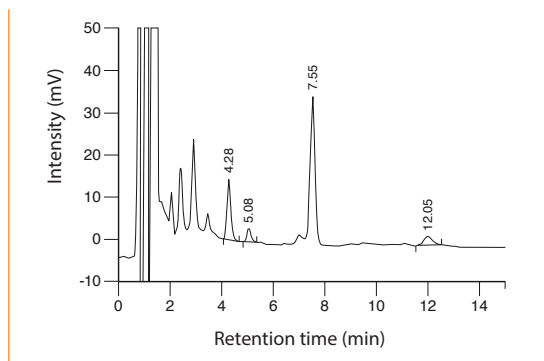
HPLC Analysis:

Inject 40 µl



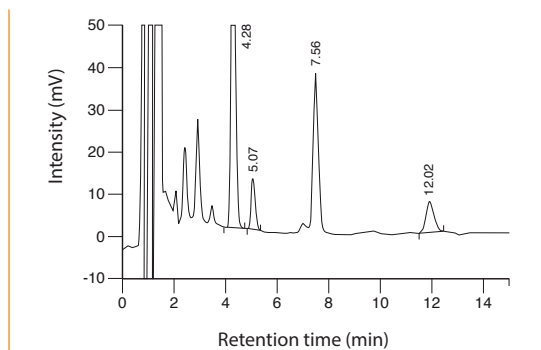
1.1.2. Biogenic Amines

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

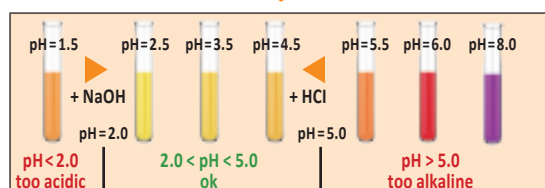
- Safe and convenient pH-adjustment
- Robust chromatography
- Detection limit: 1 µg/l



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

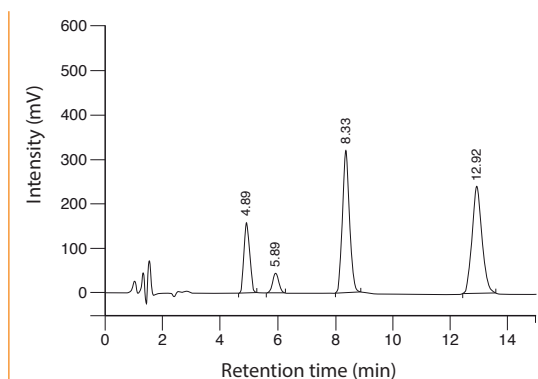
3 ml urine	5 ml Stab. Reagent S (contains colour indic.)	30 µl Internal Standard IS
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Inject 20 μ l

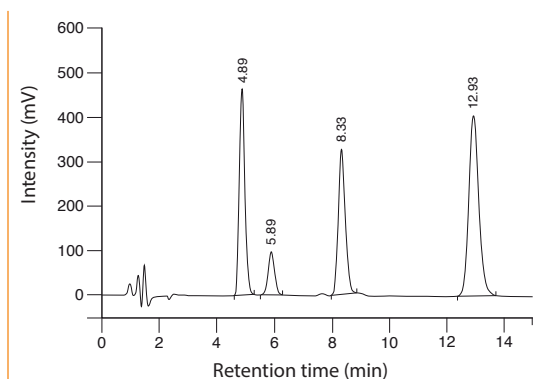
1.1.2. Biogenic Amines

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

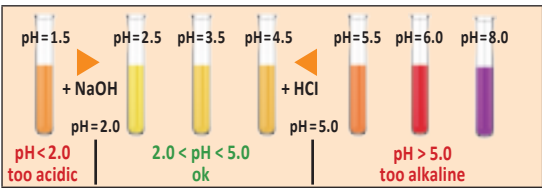
Sample Preparation*

Manual sample pretreatment

pH adjustment:

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

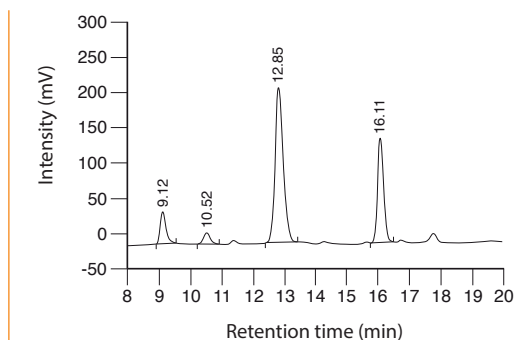
on-line Analysis:

Inject 50 µl

NE: Norepinephrine
E: Epinephrine
D: Dopamine

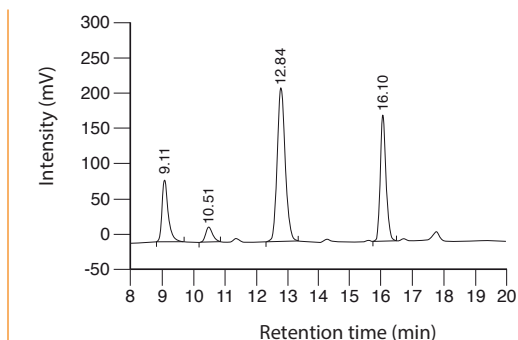
1.1.2. Biogenic Amines

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:

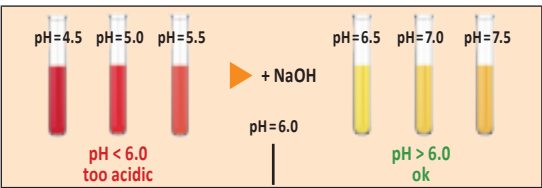
1 ml urine	20 μl Internal Standard IS
------------	---------------------------------------

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)

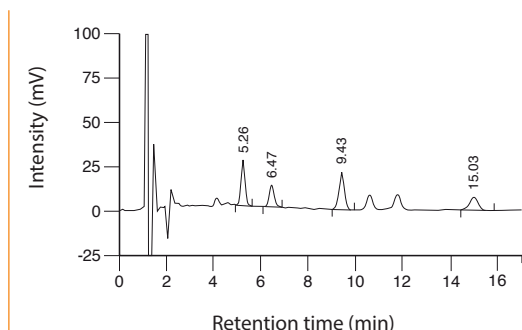
collect the eluate

HPLC Analysis:

Inject 20 μl

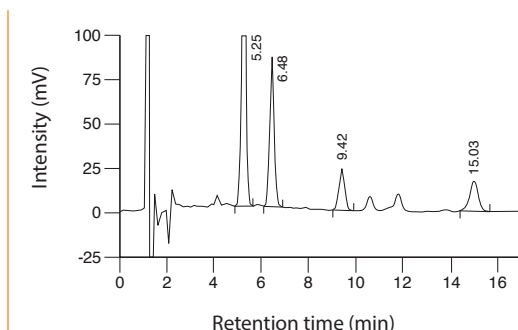
1.1.2. Biogenic Amines

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:

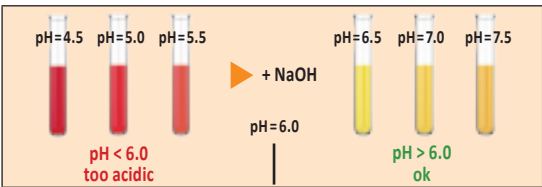
1 ml urine	20 µl Internal Standard IS
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1. adjust pH to 0.5 - 1.0
2. incubate (30 min, 90 - 100 °C)

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

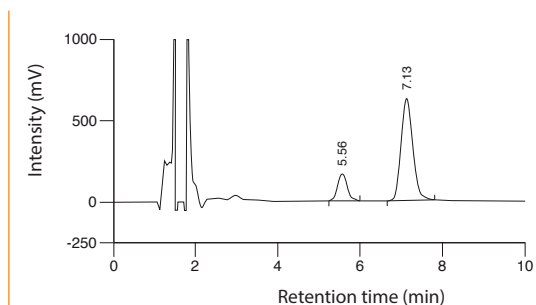


HPLC Analysis:

Inject 20 µl

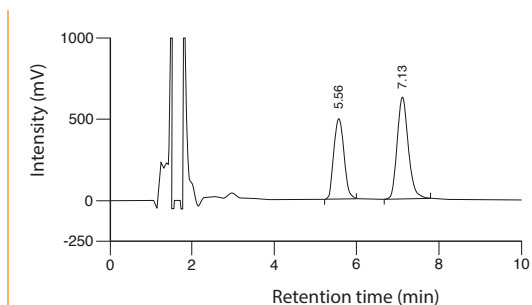
1.1.2. Biogenic Amines

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



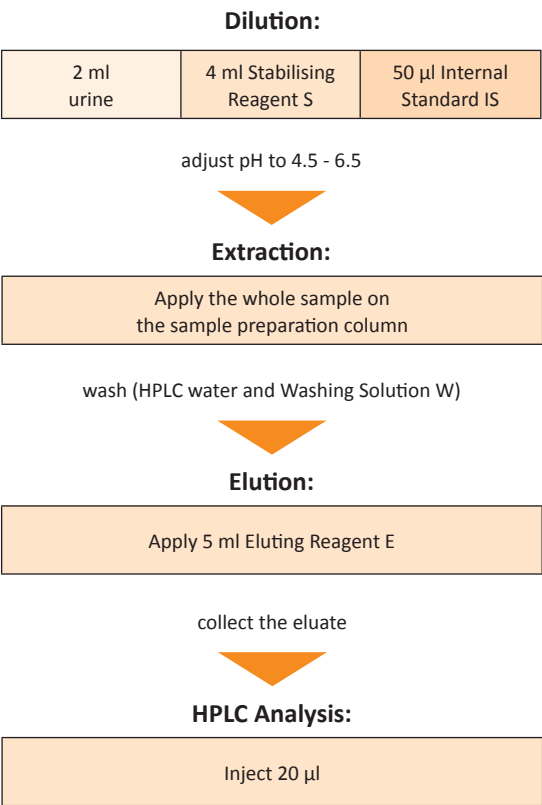
Test Data

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

HPLC Parameters

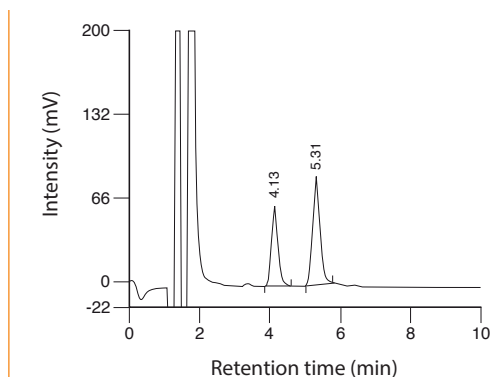
Pump:	isocratic pump, flow rate: 1.0 ml/min
Injection volume:	20 µl
Injection interval:	10 min
EC-Detector:	potential: 450 mV, sensitivity: 50 nA
HPLC-Thermostat:	30 °C

Sample Preparation



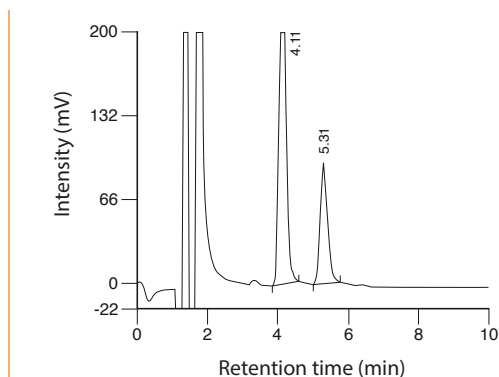
1.1.2. Biogenic Amines

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

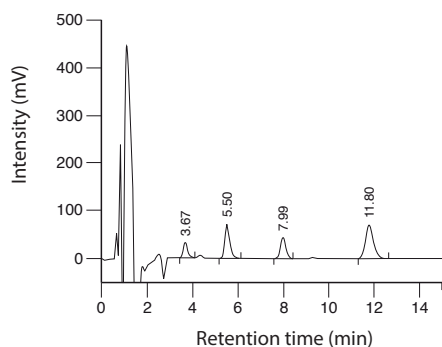
collect the eluate

HPLC Analysis:

Inject 20 µl

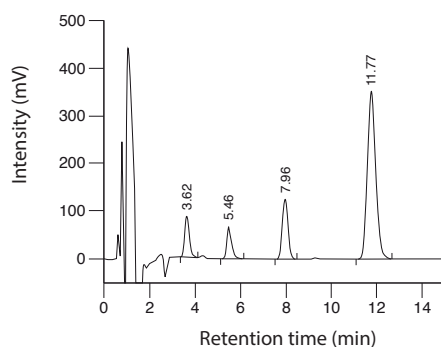
1.1.2. Biogenic Amines

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 μ l
Injection interval:	8 min
UV/VIS-Detector:	415 nm
HPLC-Thermostat:	23 $^{\circ}$ C

Sample Preparation

Hemolysis:

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

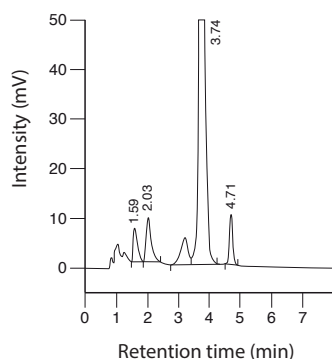


HPLC Analysis:

Inject 20 μ l

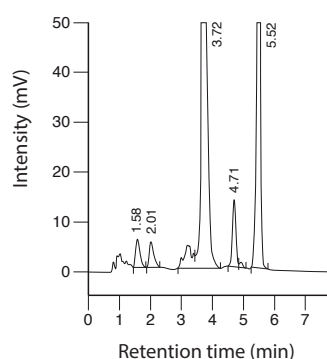
1.1.3. Hemoglobins

ClinCal® Hemolysate Calibrator (HbF/A2)



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

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



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

Ordering Information

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

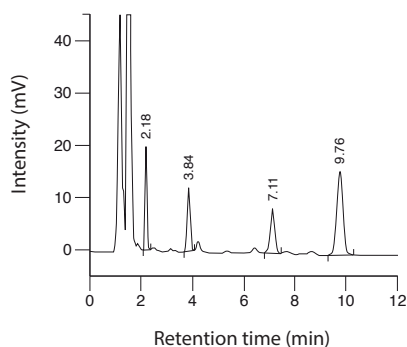


HPLC Analysis:

Inject 20 µl of the supernatant

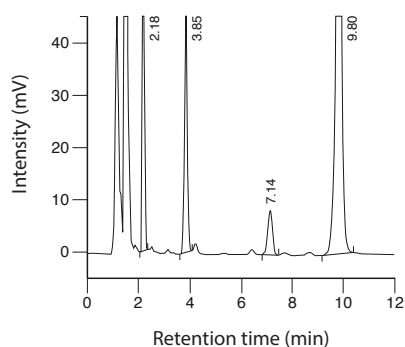
1.1.4. Metabolic Diseases

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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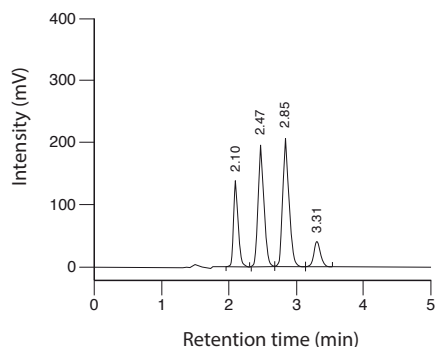
incubate (60 min, 60 °C)

HPLC Analysis:

Inject 20 µl

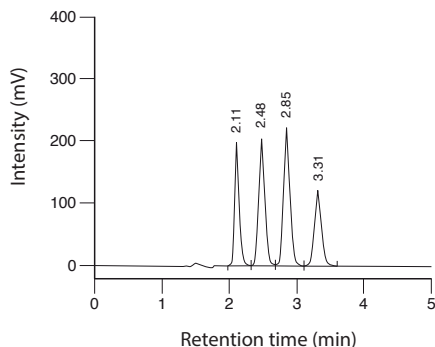
1.1.4. Metabolic Diseases

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



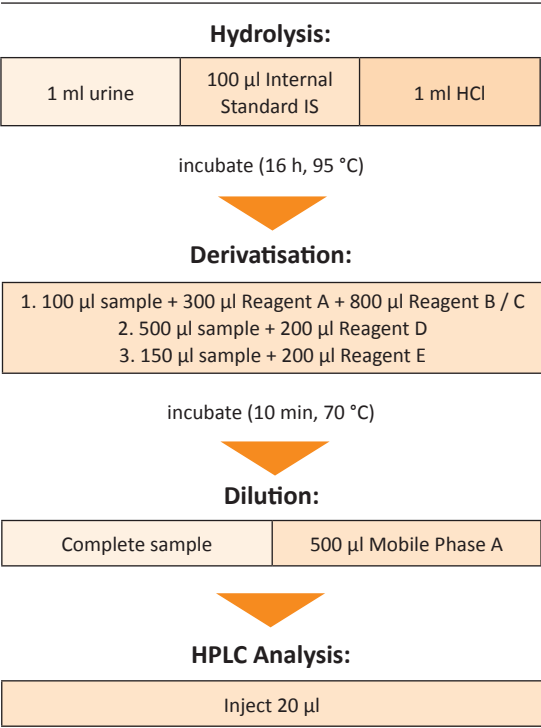
Test Data

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

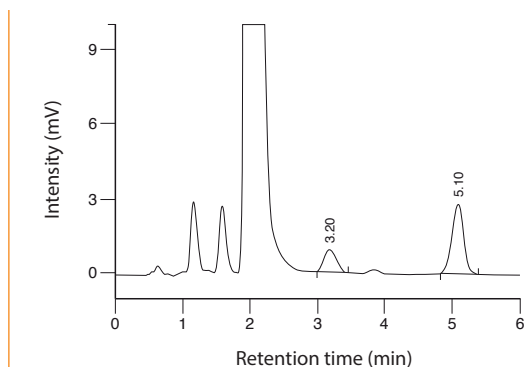
Pump:	binary gradient pump, flow rates: 1.2, 1.4 ml/min
Injection volume:	20 µl
Injection interval:	8 min
UV/VIS-Detector:	471 nm
HPLC-Thermostat:	60 °C

Sample Preparation



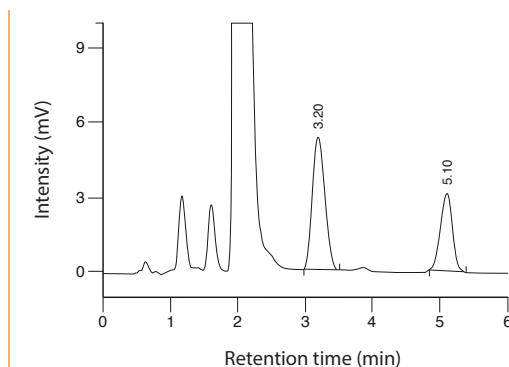
1.1.4. Metabolic Diseases

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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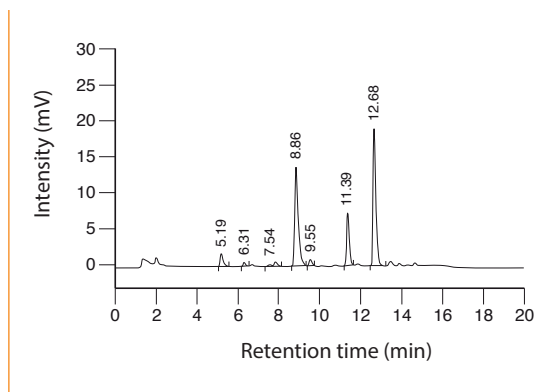
centrifuge

HPLC Analysis:

Inject 20 µl of the supernatant

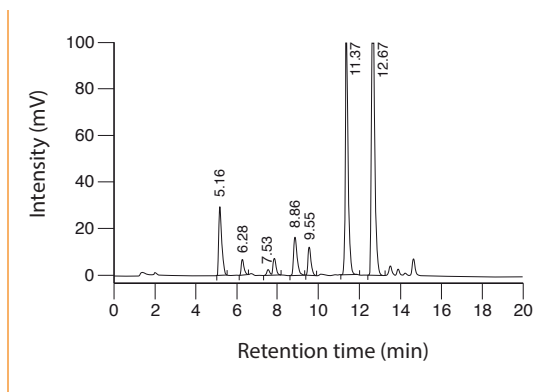
1.1.4. Metabolic Diseases

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

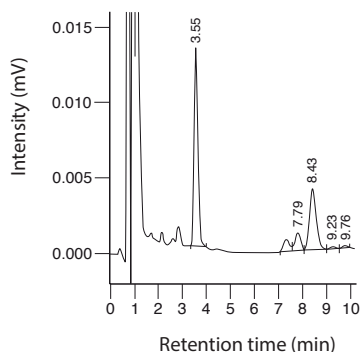
HPLC Analysis:

Inject 100 µl



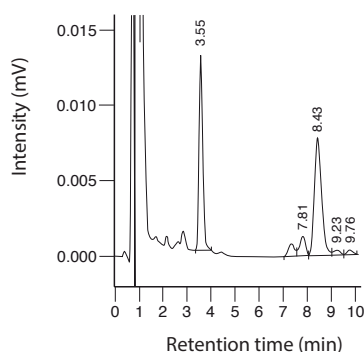
1.1.5. Oxidative Stress

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

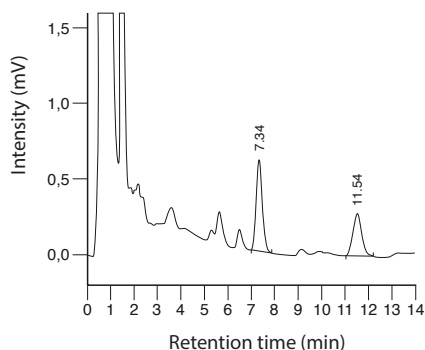
mix, centrifuge

HPLC Analysis:

Inject 30 µl of the supernatant

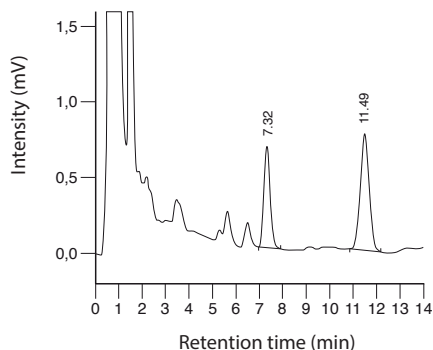
1.1.5. Oxidative Stress

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



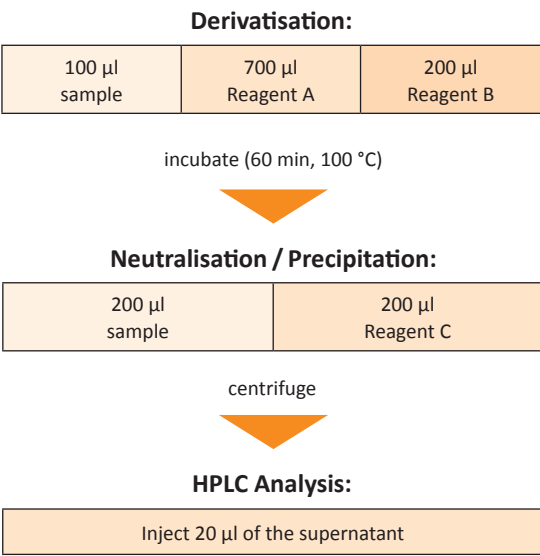
Test Data

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

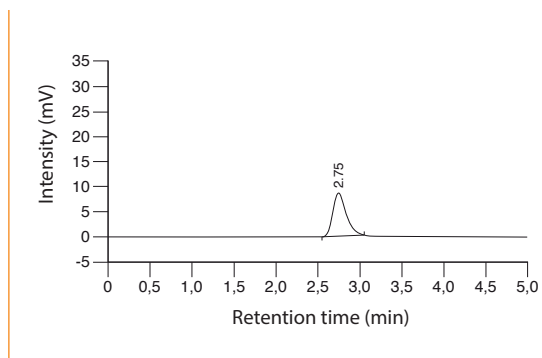
Pump:	isocratic pump, flow rate: 0.8 ml/min
Injection volume:	20 µl
Injection interval:	5 min
Fluorescence detector:	515 nm (exc.), 553 nm (em.)
HPLC-Thermostat:	30 °C

Sample Preparation



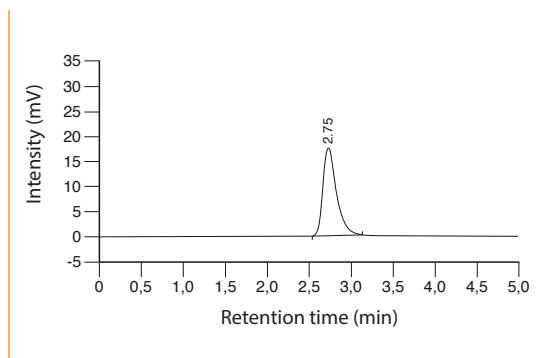
1.1.5. Oxidative Stress

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

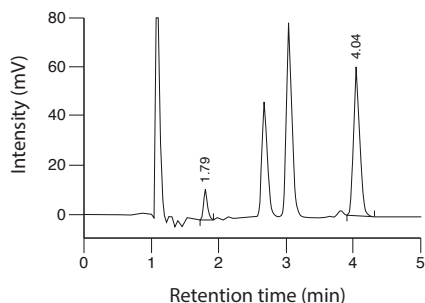


HPLC Analysis:

Inject 20 µl of the supernatant

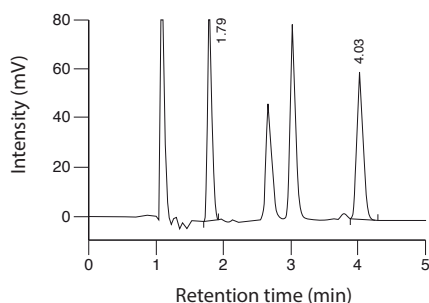
1.1.5. Oxidative Stress

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



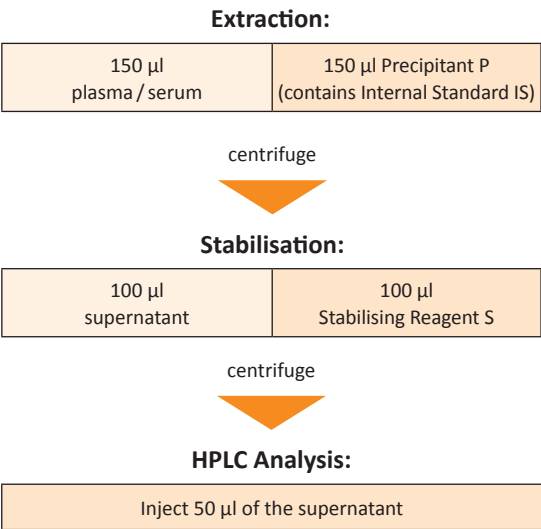
Test Data

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

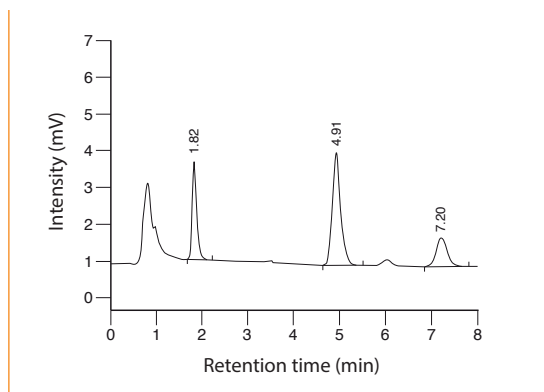
Pump:	isocratic pump, flow rate: 1.5 ml/min
Injection volume:	50 µl
Injection interval:	8 min
UV-Detector:	325 / 295 nm
HPLC-Thermostat:	30 °C

Sample Preparation



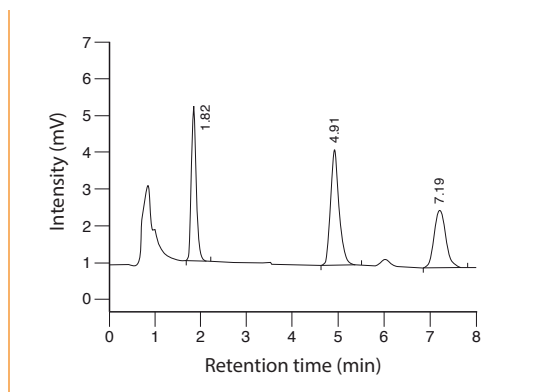
1.1.6. Vitamin Status

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

Precipitation

50 µl plasma / serum	100 µl Precipitant P (contains Internal Standard IS)	50 µl Stabilising Reagent S
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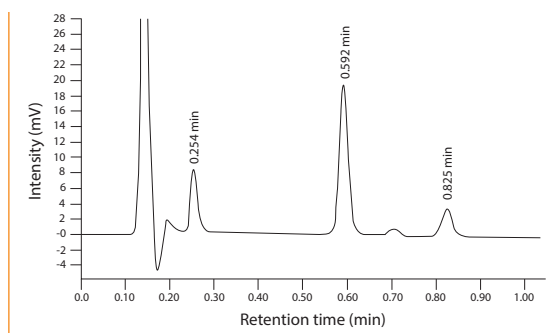
mix and centrifuge

UHPLC Analysis

Inject 5 µl of the supernatant

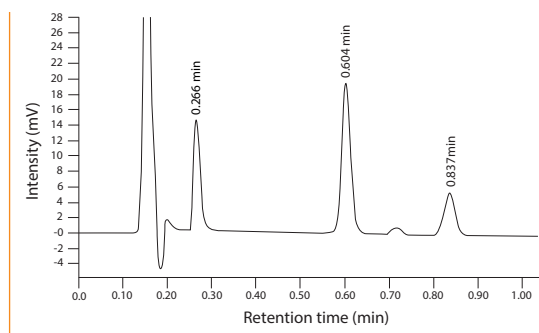
1.1.6. Vitamin Status

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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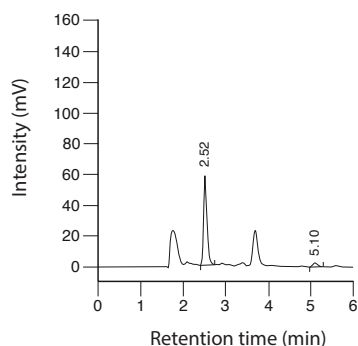
add 100 µl Reagent E

HPLC Analysis:

Inject 50 µl of the supernatant

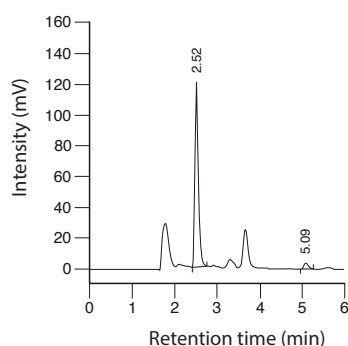
1.1.6. Vitamin Status

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

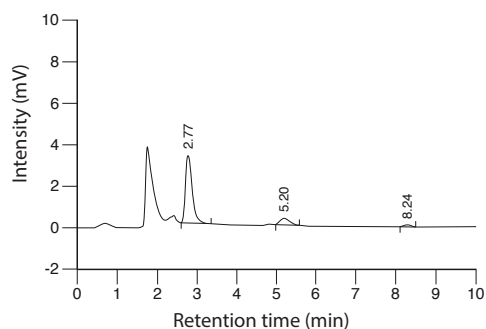


HPLC Analysis:

Inject 50 µl of the supernatant

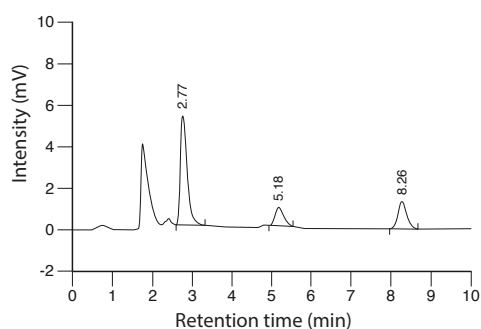
1.1.6. Vitamin Status

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

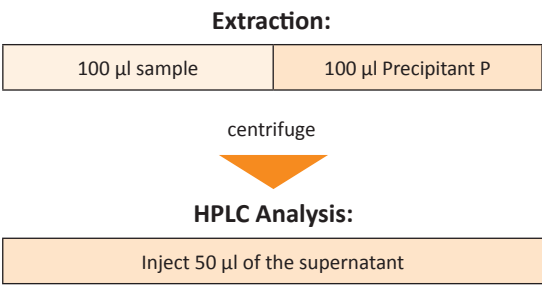
Test Data Determination from plasma / from whole blood

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

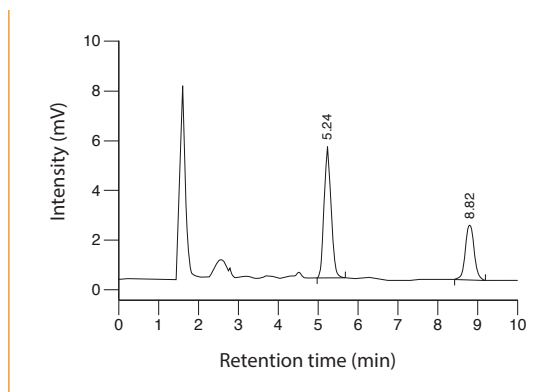
Pump:	isocratic pump, flow rate: 1.0 ml/min
Pump (Reagent N):	flow rate: 0.2 ml/min
Injection volume:	50 µl
Injection interval:	10 min
Fluorescence detector:	370 nm (exc.), 470 nm (em.)
Temperature:	25 °C (or ambient)

Sample Preparation



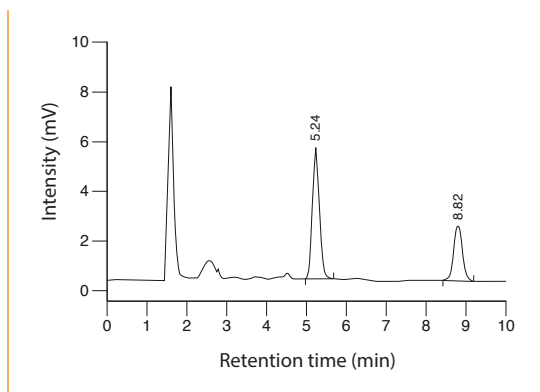
1.1.6. Vitamin Status

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

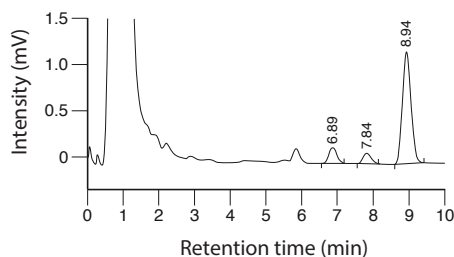
mix, centrifuge

HPLC Analysis:

Inject 50 µl of the supernatant

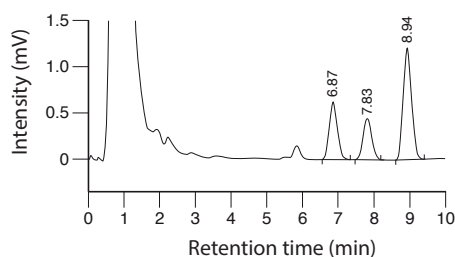
1.1.6. Vitamin Status

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

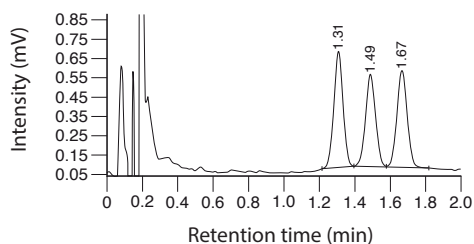
mix, centrifuge

UHPLC Analysis:

Inject 5 µl of the supernatant

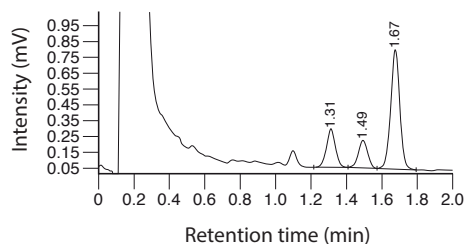
1.1.6. Vitamin Status

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

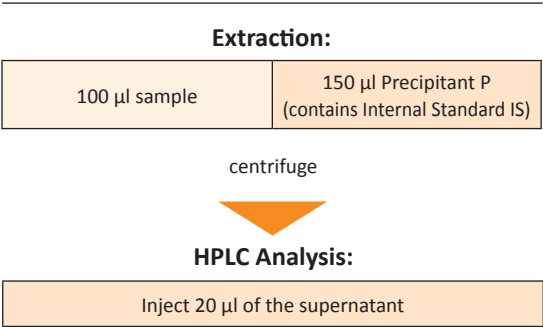
Test Data

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 %

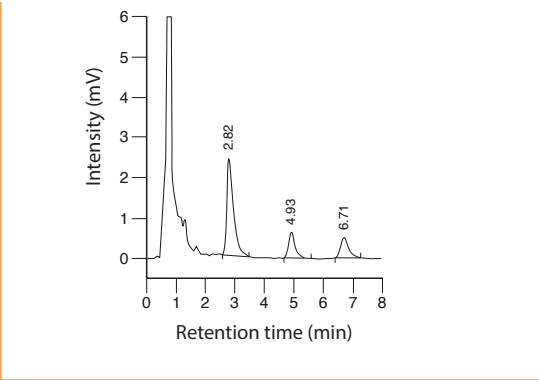
HPLC Parameters

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

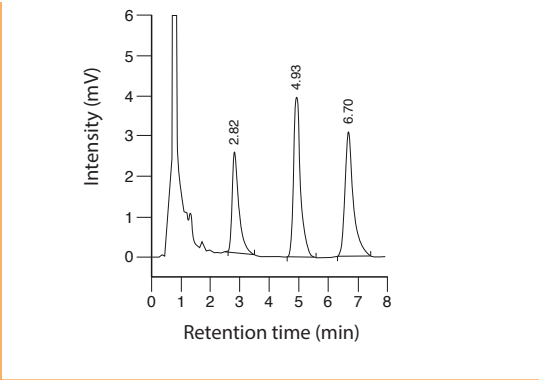


ClinChek® Serum Control, Level I



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



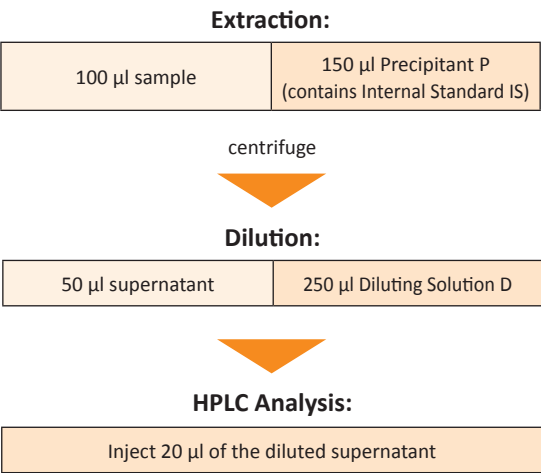
Test Data

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 %

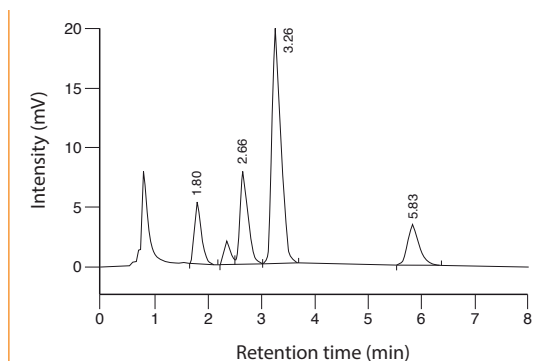
HPLC Parameters

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

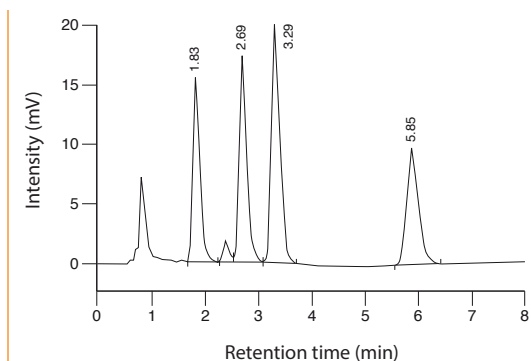


ClinChek® Plasma Control, Level I



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

Extraction:

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



Dilution:

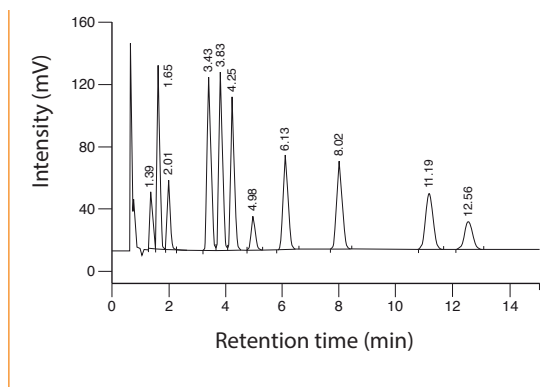
100 µl supernatant	100 µl Diluting Solution D
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HPLC Analysis:

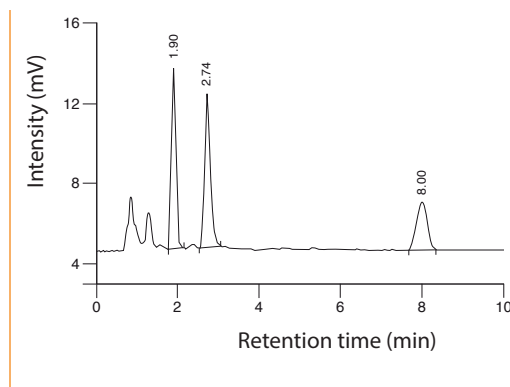
Inject 10 µl of the diluted supernatant

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

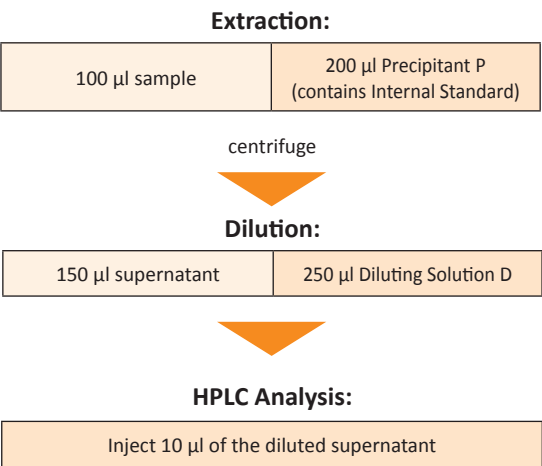
The test data are available on request.

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

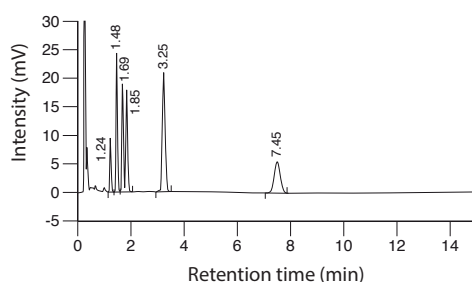
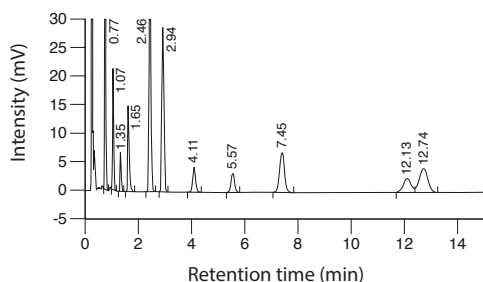
* In case samples do not contain carbamazepine and phenytoin, the injection interval can be reduced to 9 min.

Sample Preparation



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

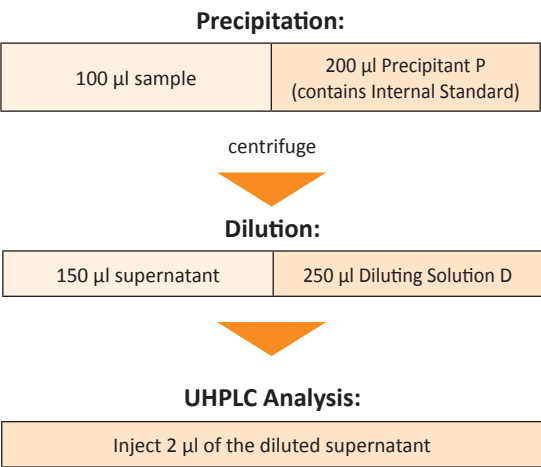
Test Data

The test data are available on request.

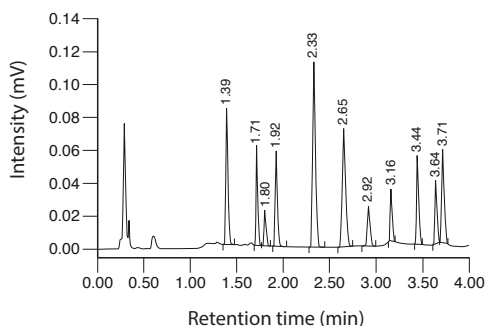
UHPLC Parameters

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

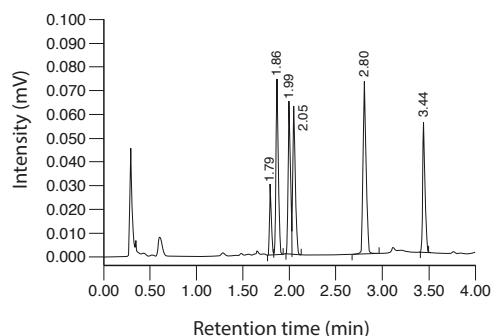


ClinChek® Serum Control, Level II (order no. 14081)



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:

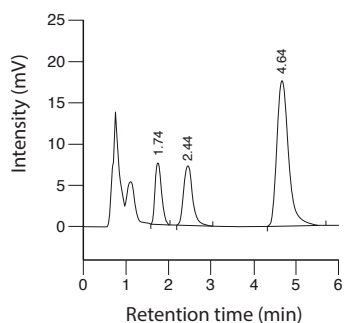
100 µl supernatant	100 µl Diluting Solution D
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HPLC Analysis:

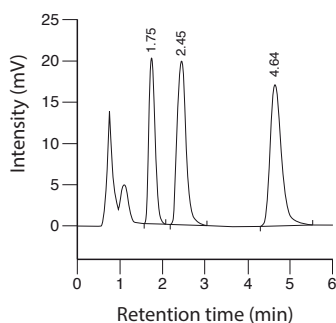
Inject 20 µl of the diluted supernatant

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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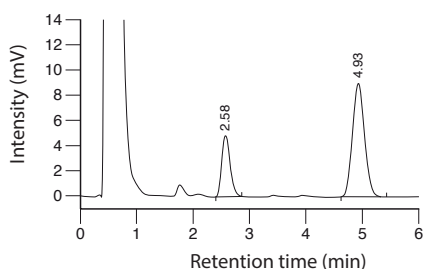


HPLC Analysis:

Inject 20 µl

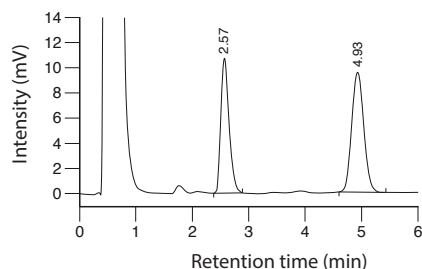
* Conditioning with Conditioning Reagent C and Washing Solution W1

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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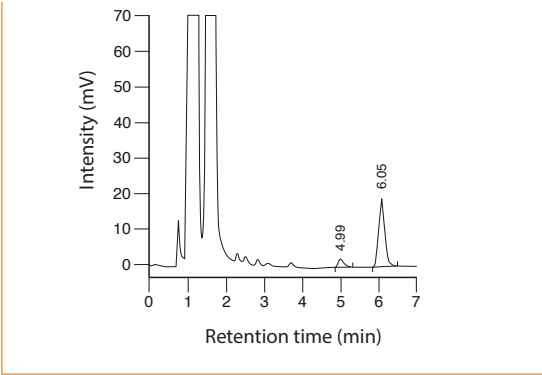
centrifuge



HPLC Analysis:

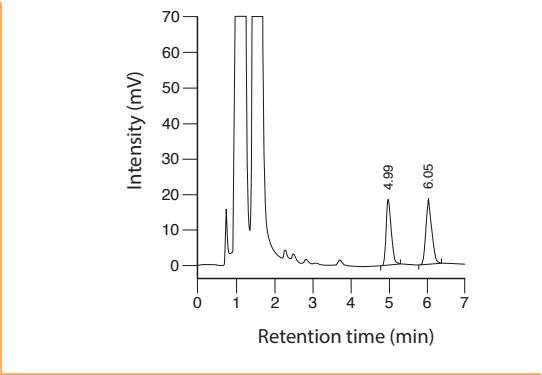
Inject 50 µl of the supernatant

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:

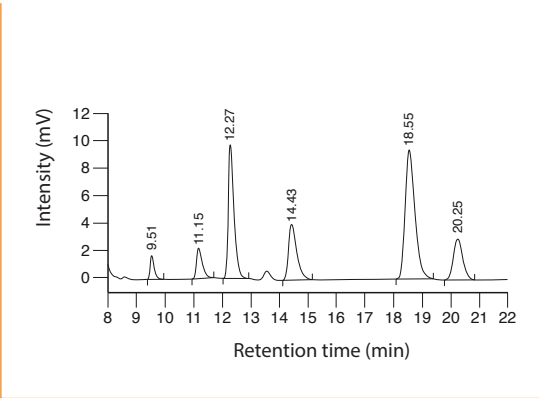
- A:** Add 20 µl Internal Standard IS/ml sample
B: Add 10 µl Internal Standard IS/ml sample

centrifuge

on-line Analysis:

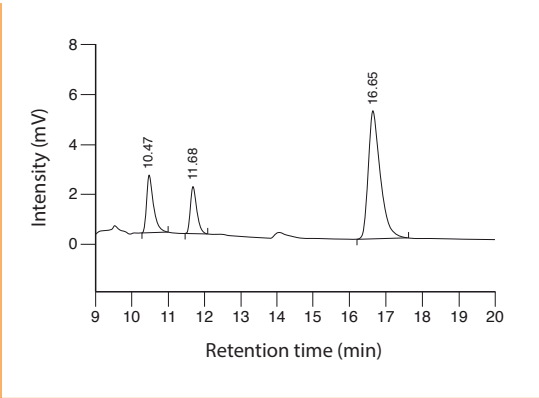
- A:** Inject 250 µl
B: Inject 750 µl

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:

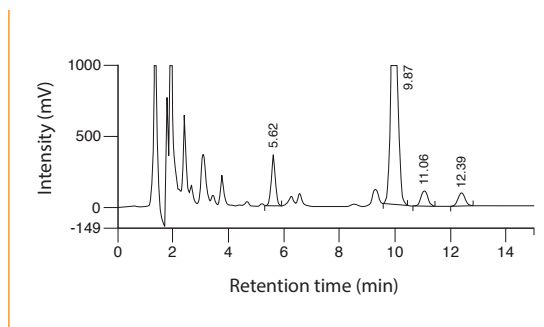
Elute with 2 ml Reagent A

collect the eluate

HPLC Analysis:

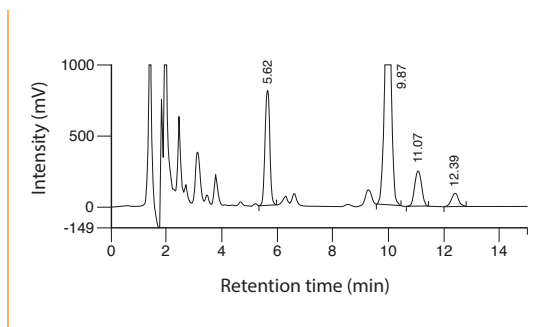
Inject 10 - 20 µl

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:

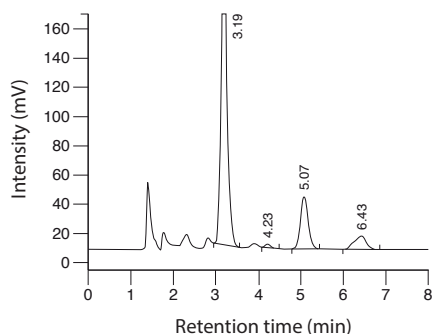
Elute with 2 ml Reagent A

collect the eluate

HPLC Analysis:

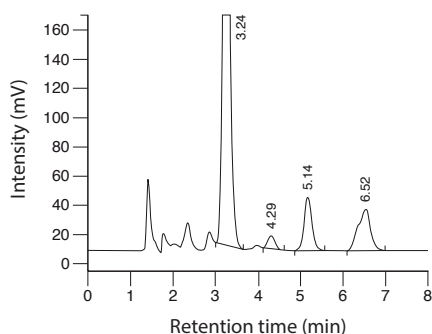
Inject 20 µl

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

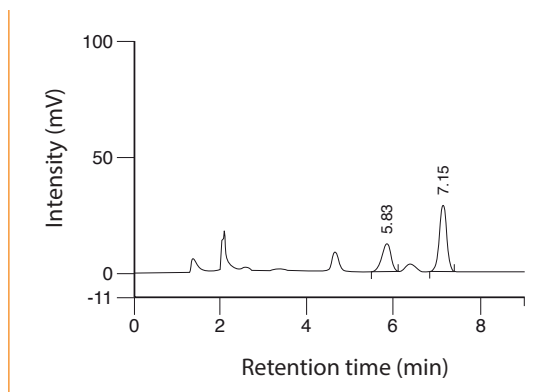
collect the eluate



HPLC Analysis:

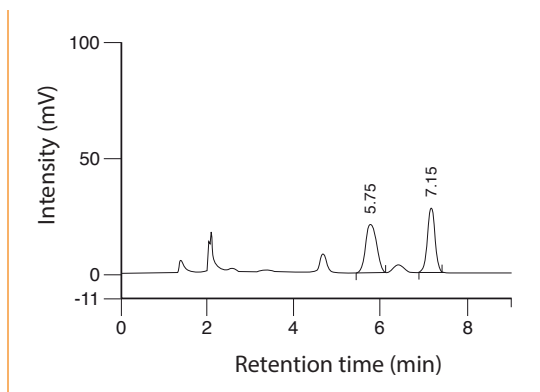
Inject 50 µl

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

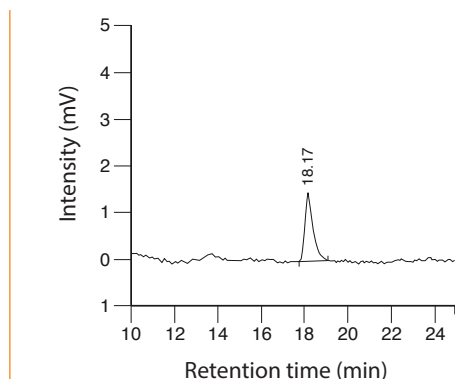


on-line Analysis:

Inject 250 µl

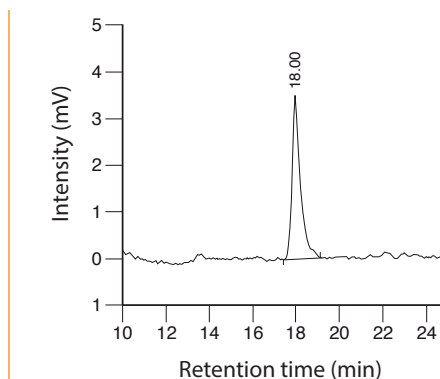
1.3.2. PAH Polycyclic Aromatic Hydrocarbons

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