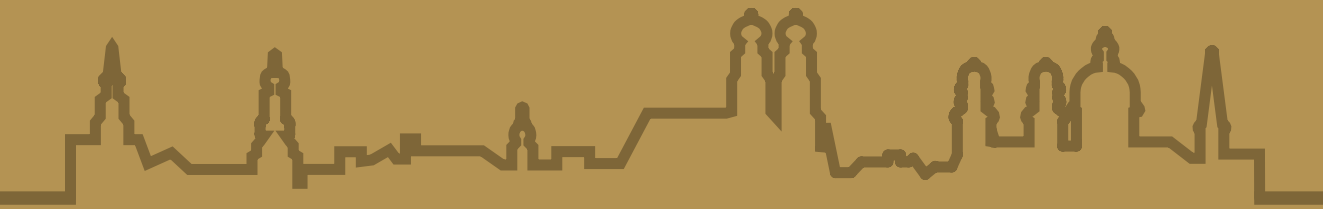


**+RECIPE**

# HPLC & LC-MS/MS

IVD Complete Kits



**40**  
Years RECIPE

Product Catalogue I  
2022/2023

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## 1.1.1 Alcoholism

# CDT in Serum

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

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

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



## Test Data

LOD: 0.1 %\*

LLOQ: 0.3 %\*

Intraassay precision: 4.2 %

Interassay precision: 4.3 %

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

## HPLC Parameters

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

Injection volume: 400 - 500 µl

Injection interval: 20 min

UV/VIS-Detector: 460 nm

HPLC-Thermostat: 40 °C

## Sample Preparation

### Stabilisation/Precipitation:

150 µl serum	30 µl Stabilising Reagent S	10 µl mixture of precipitants P1+P2
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1. incubate (30 min, 4 °C)
2. centrifuge

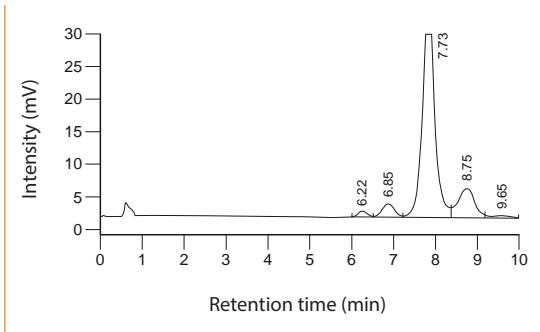
### Dilution:

100 µl supernatant	1.0 ml Diluting Solution D
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### HPLC Analysis:

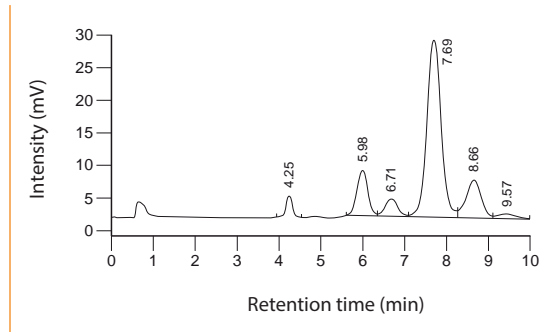
Inject 400 - 500 µl
---------------------

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
<b>21000</b>	<b>ClinRep® Complete Kit for CDT in Serum for 100 assays</b>	<b>1 pce.</b>
<b>Kit Components (order no. 21000):</b>		
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.
<b>Optional Components:</b>		
21013	Serum Calibrator Set, lyophil. (Level 1 - 2)	2 x 1 x 1 ml
21014	Test Solution	15 ml
<b>Start Accessories:</b>		
21030	Analytical Column with test chromatogram	1 pce.
21032	Cartridge incl. 1 precolumn	1 pce.
<b>Refill Service:</b>		
21031	Analytical Column with test chromatogram (original column needs to be returned)	1 pce.
<b>Accessories:</b>		
21033	Precolumns	5 pcs.
FK5810	PEEK tubing (connection of prefilter and column)	1 pce.
RC2002	Sodium-Hypochlorite-Solution (5 %)	12 ml
<b>ClinChek® Controls:</b>		
21080	Serum Control, lyophil., Level I	10 x 1 ml
21081	Serum Control, lyophil., Level II	10 x 1 ml
21082	Serum Control, lyophil., Level I, II	2 x 5 x 1 ml

## 1.1.1 Alcoholism

# CDT in Serum

### ► on-line Analysis

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

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

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



### Test Data

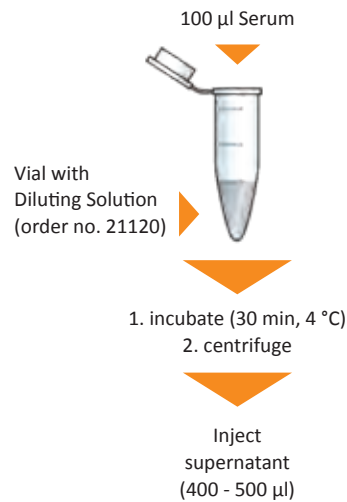
LOD:	0.1 %*
LLOQ:	0.3 %*
Intraassay precision:	4.5 %
Interassay precision:	3.9 %

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

### HPLC Parameters

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

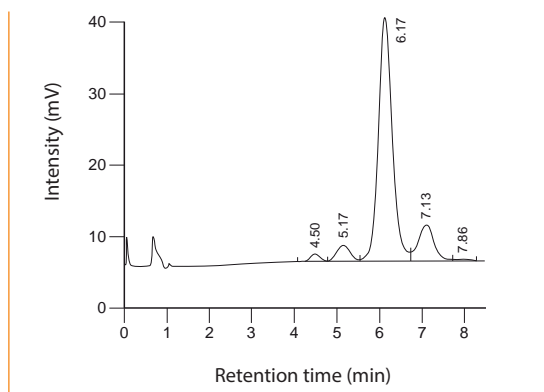
### Sample Pretreatment



**One step  
sample pretreatment!**

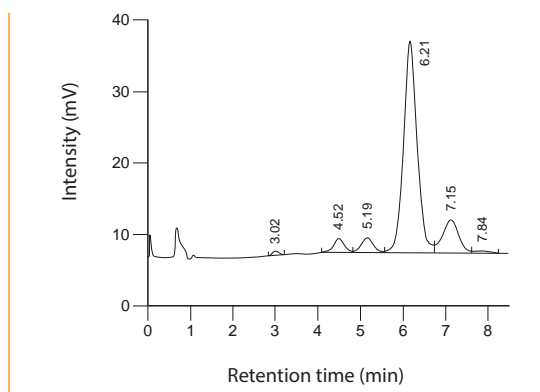
## 1.1.1 Alcoholism

Native sample, normal range



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

Native sample, pathological range



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

## Ordering Information

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

## 1.1.1 Alcoholism

# CDT in Serum

### ► automated on-line Analysis

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

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

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



## Test Data

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

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

## HPLC Parameters

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

## Sample Pretreatment (Liquid Handling System)

### Dilution:

500 µl Diluting Solution D	50 µl serum
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1. incubate (30 min, 4 °C)
2. centrifuge

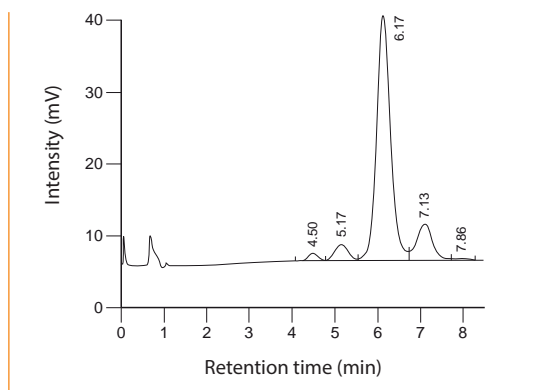
### on-line Analysis:

Inject 400 µl



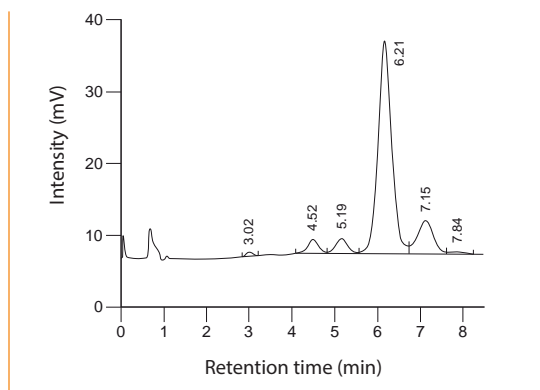
## 1.1.1 Alcoholism

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

## Catecholamines in Plasma

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

- Reliable sample preparation
- Quick and safe quantification

### Test Data

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

### HPLC Parameters

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

### Sample Preparation

#### Extraction:

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

wash  
(3 x 1 ml Washing Solution W)

#### Elution:

Elute with 120 µl Eluting Reagent E

collect the eluate

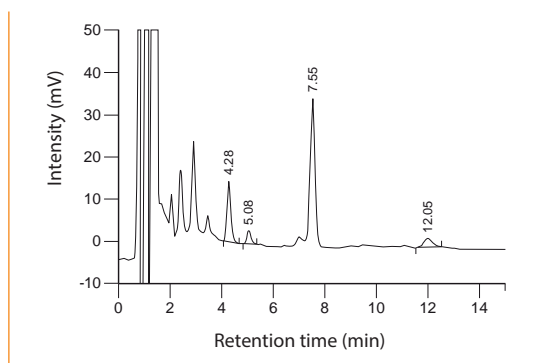
#### HPLC Analysis:

Inject 40 µl



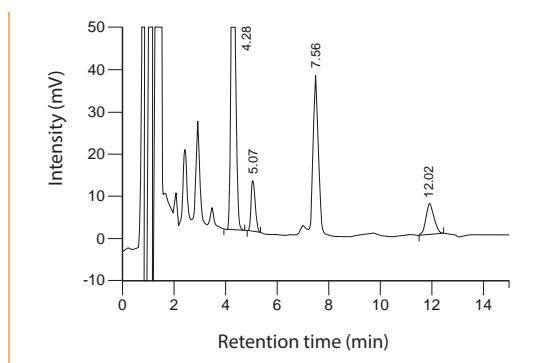
## 1.1.2 Biogenic Amines

ClinChek® Plasma Control, Level I



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

ClinChek® Plasma Control, Level II



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

## Ordering Information

Order No.	Description	Quantity
<b>1000</b>	<b>ClinRep® Complete Kit for Catecholamines in Plasma for 250 assays</b>	<b>1 pce.</b>
<b>Kit Components (order no. 1000):</b>		
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.
<b>Start Accessories:</b>		
1030	Analytical Column with test chromatogram	1 pce.
<b>ClinChek® Controls:</b>		
<b>8810</b>	Plasma Control, lyophil., Level I	10 x 5 ml
<b>8811</b>	Plasma Control, lyophil., Level II	10 x 5 ml
<b>8809</b>	Plasma Control, lyophil., Level I, II	2 x 5 x 5 ml

# Catecholamines in Urine

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

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



## Test Data

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

## HPLC Parameters

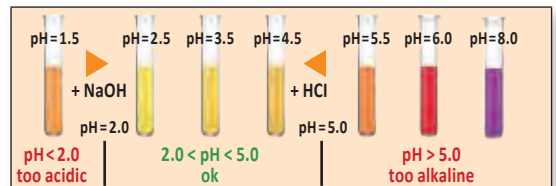
Isocratic Pump:	flow rate: 1.0 ml/min
Injection vol./int.:	20 µl / 15 min
EC-Detector:	pot.: 500 mV, sen.: 10 nA
HPLC-Thermostat:	30 °C

## Sample Preparation

### Addition of IS/ pH adjustment:

3 ml urine	5 ml Stab. Reagent S (contains colour indic.)	30 µl Internal Standard IS
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adjust with 1 M NaOH, until the indicator switches to yellow



### Extraction:

Apply the whole sample on the sample preparation column

wash (HPLC water)

### Elution:

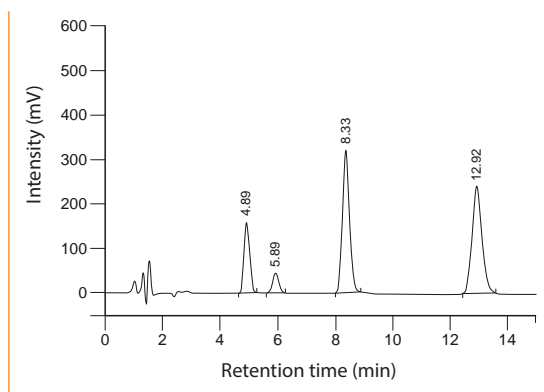
Apply 6 ml Eluting Reagent E

### HPLC Analysis:

Inject 20 µl

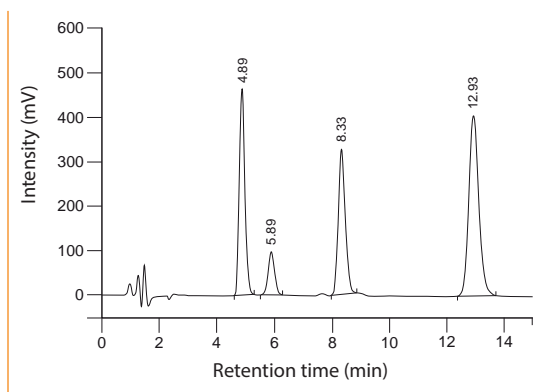
## 1.1.2 Biogenic Amines

ClinChek® Urine Control, Level I



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

ClinChek® Urine Control, Level II



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

## Ordering Information

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

## 1.1.2 Biogenic Amines

# Catecholamines in Urine

► with Gilson® ASPEC™

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

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



## Test Data

Test data are available on request.

## HPLC Parameters

Identical with order no. 2000

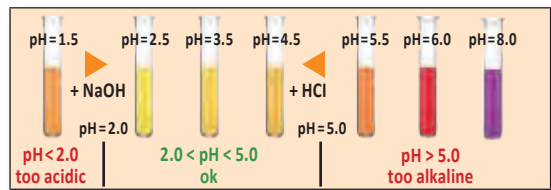
## Sample Preparation\*

### Manual sample pretreatment

#### pH adjustment:

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

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



### Automated sample preparation

#### with Gilson® ASPEC™

#### Addition of IS:

Add 30 µl Internal Standard IS to the sample

#### Extraction:

Apply 6 ml sample on the sample preparation column

wash (HPLC water)

#### Elution:

Apply 4 ml Eluting Reagent E

#### HPLC Analysis:

Inject 20 µl

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

## Ordering Information

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

# Metanephrines in Urine, *advanced*

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

- Ultra fast chromatography
- Improved internal standard
- Safe and convenient pH-adjustment



## Test Data

Test data are available on request.

## HPLC Parameters

Isocratic Pump: flow rate 1.3 ml/min  
Injection vol./int.: 20  $\mu\text{l}$ /8 min  
EC-Detector: pot. 700 mV, sen.: 50 nA  
HPLC-Thermostat: 30  $^{\circ}\text{C}$

## Sample Preparation

### Hydrolysis:

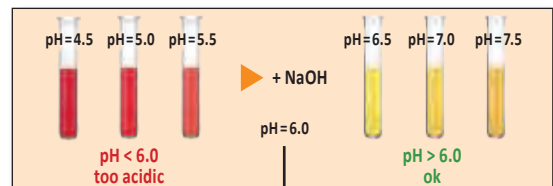
1 ml urine	20 $\mu\text{l}$ Internal Standard IS
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1. adjust pH to 0.5 - 1.0
2. incubate (30 min, 90 - 100  $^{\circ}\text{C}$ )

### pH adjustment:

Add 4 ml Diluting Solution D (contains colour indicator)

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



### Extraction:

Apply the whole sample on the  
sample preparation column

### Washing:

Wash (HPLC water and Washing Solution W)

### Elution:

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

collect the eluate

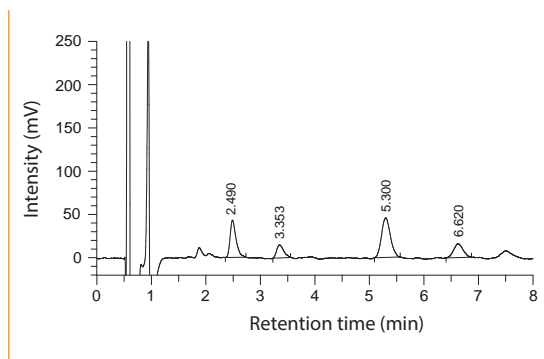
### HPLC Analysis:

Inject 20  $\mu\text{l}$



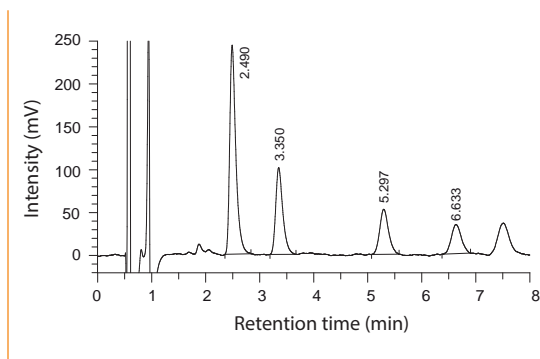
## 1.1.2 Biogenic Amines

ClinChek® Urine Control, Level I



Normetanephrine: 2.490 min, Metanephrine: 3.353 min, IS: 5.300 min, 3-Methoxytyramine: 6.620 min

ClinChek® Urine Control, Level II



Normetanephrine: 2.490 min, Metanephrine: 3.350 min, IS: 5.297 min, 3-Methoxytyramine: 6.633 min

### Ordering Information

Order No.	Description	Quantity
4500	ClinRep® Complete Kit for Metanephrines in Urine, advanced for 100 assays	1 pce.
<b>Kit components (order no. 4500):</b>		
4510	Mobile Phase	1000 ml
4511	Standard Solution	10 ml
4512	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.
<b>Start Accessories:</b>		
4530	Analytical Column with test chromatogram	1 pce.
<b>Accessories:</b>		
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.
<b>ClinChek® Controls:</b>		
8820	Urine Control, lyophil., Level I	10 x 8 ml
8821	Urine Control, lyophil., Level II	10 x 8 ml
8822	Urine Control, lyophil., Level I, II	2 x 5 x 8 ml

## 1.1.2 Biogenic Amines

# Metanephrines in Urine, *advanced*

► with Gilson® ASPEC™

Metanephrines are important parameters for the diagnosis of tumors of the sympathoadrenal system. In addition to the ClinRep® Complete Kit with manual sample preparation (order no. 4500) RECIPE offers ClinRep® Complete Kits for automated sample preparation with Gilson® robotic systems.

- Automated sample preparation



## Test Data

Test data are available on request.

## HPLC Parameters

Identical with order no. 4500

## Sample Preparation\*

### Manual sample pretreatment

#### Hydrolysis:

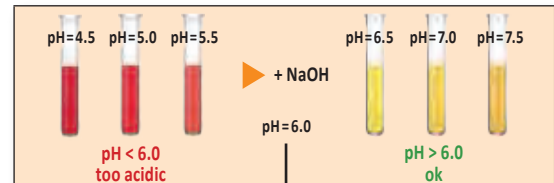
1 ml urine	20 µl Internal Standard IS
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1. adjust pH to 0.5 - 1.0
2. incubate (30 min, 90 - 100 °C)

#### 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™

#### Extraction:

Apply 2.5 ml sample to the sample preparation column

wash (HPLC water and Washing Solution W)

#### Elution:

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

collect the eluate

#### HPLC Analysis:

Inject 20 µl

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

## Ordering Information

Order No.	Description	Quantity
<b>4600</b>	<b>ClinRep<sup>®</sup> Complete Kit for Metanephrines in Urine with Gilson<sup>®</sup> ASPEC<sup>™</sup> for 100 assays</b>	<b>1 pce.</b>
<b>Kit components (order no. 4600):</b>		
<b>4510</b>	Mobile Phase	1000 ml
<b>4511</b>	Standard Solution	10 ml
<b>4512</b>	Internal Standard IS	3 ml
<b>4013</b>	Urine Calibrator, lyophil.	5 x 8 ml
<b>4120</b>	Sample Preparation Columns	2 x 4120 (2 x 50 pcs.)
<b>4022</b>	Diluting Solution D	400 ml
<b>4023</b>	Washing Solution W	400 ml
<b>4124</b>	Eluting Reagent E	250 ml
<b>4125</b>	Stabilising Reagent S	80 ml
	Manual	1 pce.
	Quick Reference	1 pce.
<b>Start Accessories:</b>		
<b>4530</b>	Analytical Column with test chromatogram	1 pce.
<b>Accessories:</b>		
<b>FK6300</b>	Reagent tubes (100 x 16 mm) with screw cap and o-ring, PP, autoclavable up to 121 °C	50 pcs.
<b>ClinChek<sup>®</sup> Controls:</b>		
<b>8820</b>	Urine Control, lyophil., Level I	10 x 8 ml
<b>8821</b>	Urine Control, lyophil., Level II	10 x 8 ml
<b>8822</b>	Urine Control, lyophil., Level I, II	2 x 5 x 8 ml

## Serotonin in Plasma

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

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



### Test Data

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

### HPLC Parameters

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

### Sample Preparation

#### Precipitation:

200 µl plasma	10 µl Internal Standard IS
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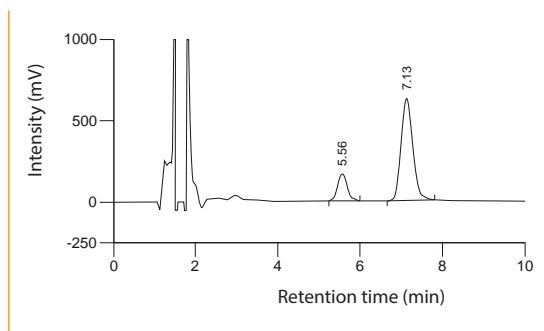
1. add 200 µl Precipitant P
2. centrifuge

#### HPLC Analysis:

Inject 20 µl
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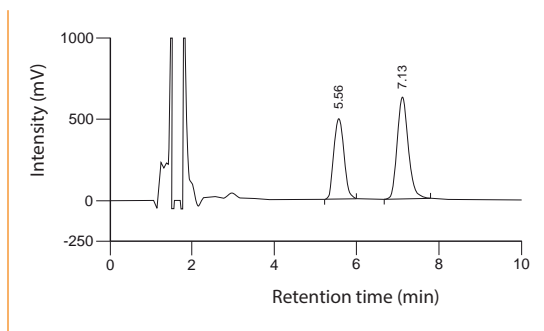
## 1.1.2 Biogenic Amines

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

# Serotonin in Urine

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

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



## Test Data

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

## HPLC Parameters

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

## Sample Preparation

### Dilution:

2 ml urine	4 ml Stabilising Reagent S	50 µl Internal Standard IS
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adjust pH to 4.5 - 6.5



### Extraction:

Apply the whole sample on  
the sample preparation column

wash (HPLC water and Washing Solution W)



### Elution:

Apply 5 ml Eluting Reagent E

collect the eluate

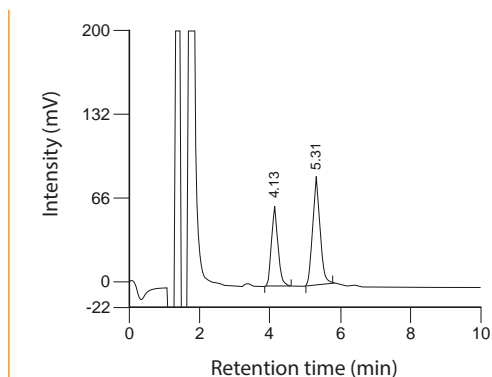


### HPLC Analysis:

Inject 20 µl

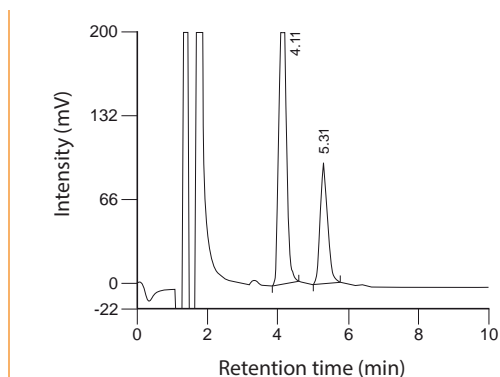
## 1.1.2 Biogenic Amines

ClinChek® Urine Control, Level I



Serotonin: 4.13 min, IS: 5.31 min

ClinChek® Urine Control, Level II



Serotonin: 4.11 min, IS: 5.31 min

## Ordering Information

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

## 1.1.2 Biogenic Amines

# VMA, HVA and 5-HIAA in Urine, *advanced*

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

Also available: Complete kits for automated sample preparation.

- Highly selective sample preparation
- Reliable test procedure
- Two internal standards



## Test Data

Linearity:	VMA: 0.5 - 100 mg/l HVA: 0.5 - 100 mg/l 5-HIAA: 0.3 - 50 mg/l
Recovery:	VMA: 59 - 66 % HVA: 67 - 78 % 5-HIAA: 93 - 97 %
LOD:	VMA: 0.1 mg/l HVA: 0.1 mg/l 5-HIAA: 0.1 mg/l
LLOQ:	VMA: 0.3 mg/l HVA: 0.3 mg/l 5-HIAA: 0.3 mg/l
Precision	
Intraassay:	VMA: 3.6 % HVA: 7.0 % 5-HIAA: 3.2 %
Interassay:	VMA: 6.1 % HVA: 7.9 % 5-HIAA: 6.2 %

## HPLC Parameters

Isocratic Pump:	flow rate: 1.3 ml/min
Injection vol. / int.:	20 µl / 17 min
EC-Detector:	pot.: 750 mV, sen.: 50 nA
HPLC-Thermostat:	30 °C

## Sample Preparation

### Addition of IS:

50 µl urine

1 ml Internal Standard IS

### Extraction:

Apply the whole sample on the sample preparation column

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

### Elution:

Apply 2 ml Eluting Reagent E

collect the eluate

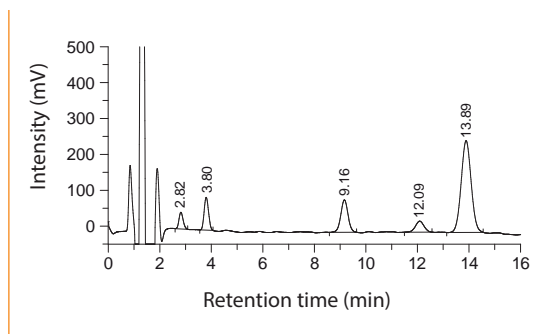
### HPLC Analysis:

Inject 20 µl



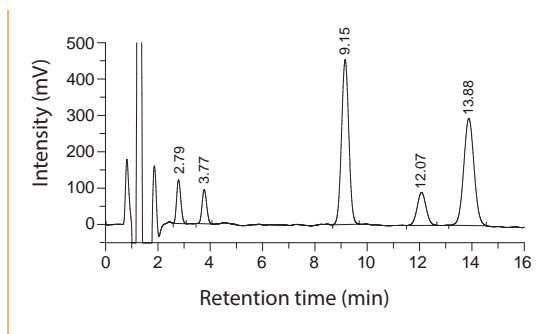
## 1.1.2 Biogenic Amines

ClinChek® Urine Control, Level I



VMA: 2.82 min, IS 1: 3.80 min, 5-HIAA: 9.16 min,  
HVA: 12.09 min, IS 2: 13.89 min

ClinChek® Urine Control, Level II



VMA: 2.79 min, IS 1: 3.77 min, 5-HIAA: 9.15 min,  
HVA: 12.07 min, IS 2: 13.88 min

### Ordering Information

Order No.	Description	Quantity
<b>3500</b>	<b>ClinRep® Complete Kit for VMA, HVA, 5-HIAA in Urine, advanced for 100 assays</b>	<b>1 pce.</b>
<b>Kit components (order no. 3500):</b>		
<b>3510</b>	Mobile Phase	1000 ml
<b>3511</b>	Standard Solution, lyophil., with Reconstitution Solution R	5 x 1 ml
<b>3512</b>	Internal Standard IS	100 ml
<b>3013</b>	Urine Calibrator, lyophil.	5 x 5 ml
<b>3020</b>	Sample Preparation Columns	2 x 3020 (2 x 50 pcs.)
<b>3021</b>	Ammonia Solution A	100 ml
<b>3022</b>	Boric Acid Solution B	2 x 3022 (2 x 300 ml)
<b>3023</b>	Eluting Reagent E	2 x 3023 (2 x 100 ml)
	Manual	1 pce.
	Quick Reference	1 pce.
<b>Start Accessories:</b>		
<b>3530</b>	Analytical Column with test chromatogram	1 pce.
<b>ClinChek® Controls:</b>		
<b>8820</b>	Urine Control, lyophil., Level I	10 x 8 ml
<b>8821</b>	Urine Control, lyophil., Level II	10 x 8 ml
<b>8822</b>	Urine Control, lyophil., Level I, II	2 x 5 x 8 ml

## 1.1.2 Biogenic Amines

# VMA, HVA and 5-HIAA in Urine, *advanced*

► with Gilson® ASPEC™

VMA, HVA and 5-HIAA are important parameters for the diagnosis of neuroblastoma and carcinoid tumors. In addition to the ClinRep® Complete Kit with manual sample preparation (order no. 3500) RECIPE offers ClinRep® Complete Kits for automated sample preparation with Gilson® robotic systems.

- Automated sample preparation
- Injection interval: 15 min

## Test Data

Test data are available on request.

## HPLC Parameters

Identical with order no. 3500

## Sample Preparation\*

**Automated sample preparation  
with Gilson® ASPEC™**

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

**Elution:**

Apply 2 ml Eluting Reagent E
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**HPLC Analysis:**

Inject 20 µl
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\* The indicated sample/reagent volumes are exemplified for the ASPEC™.



## Ordering Information

Order No.	Description	Quantity
<b>3600</b>	<b>ClinRep<sup>®</sup> Complete Kit for VMA, HVA, 5-HIAA in Urine with Gilson<sup>®</sup> ASPEC<sup>™</sup> for 100 assays</b>	<b>1 pce.</b>
<b>Kit components (order no. 3600):</b>		
<b>3510</b>	Mobile Phase	1000 ml
<b>3511</b>	Standard Solution, lyophil., with Reconstitution Solution R	5 x 1 ml
<b>3512</b>	Internal Standard IS	100 ml
<b>3013</b>	Urine Calibrator, lyophil.	5 x 5 ml
<b>3120</b>	Sample Preparation Columns	2 x 3120 (2 x 50 pcs.)
<b>3021</b>	Ammonia Solution A	100 ml
<b>3022</b>	Boric Acid Solution B	2 x 3022 (2 x 300 ml)
<b>3023</b>	Eluting Reagent E	2 x 3023 (2 x 100 ml)
	Manual	1 pce.
	Quick Reference	1 pce.
<b>Start Accessories:</b>		
<b>3530</b>	Analytical Column with test chromatogram	1 pce.
<b>ClinChek<sup>®</sup> Controls:</b>		
<b>8820</b>	Urine Control, lyophil., Level I	10 x 8 ml
<b>8821</b>	Urine Control, lyophil., Level II	10 x 8 ml
<b>8822</b>	Urine Control, lyophil., Level I, II	2 x 5 x 8 ml

# Aromatic Amino Acids in Plasma

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

### Important notice:

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

- Easy sample preparation
- High analytical sensitivity
- Reliable monitoring



## Test Data

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

## HPLC Parameters

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

## Sample Preparation

### Precipitation:

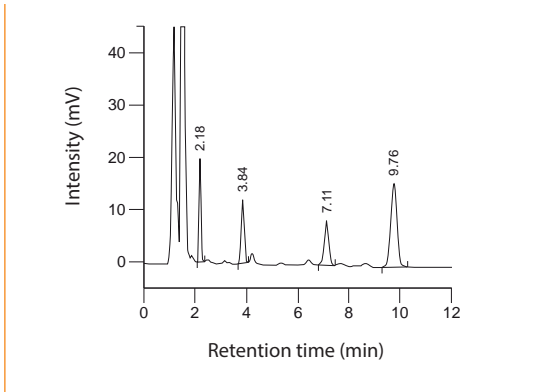
Pipette 50 µl sample into a vial with order no. 10020  
(contains Precipitant P and Internal Standard)

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

### HPLC Analysis:

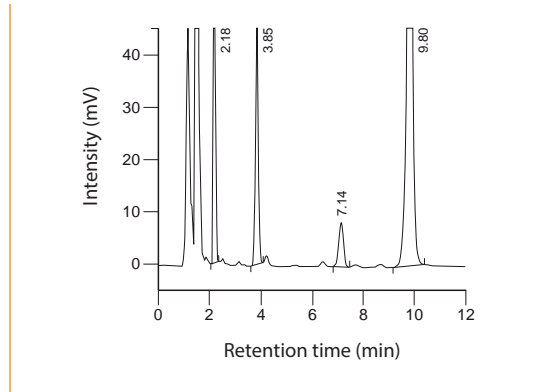
Inject 20 µl of the supernatant

ClinChek® Plasma Control, Level I



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

ClinChek® Plasma Control, Level II



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

**Ordering Information**

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

# Homocysteine in Plasma

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

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



## Test Data

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

## HPLC Parameters

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

## Sample Preparation

### Reduction:

100 $\mu\text{l}$ plasma	25 $\mu\text{l}$ Internal Standard IS	25 $\mu\text{l}$ Reagent A
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### Precipitation:

150 $\mu\text{l}$ reduced sample	100 $\mu\text{l}$ Reagent B
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centrifuge

### Derivatisation:

50 $\mu\text{l}$ supernatant	100 $\mu\text{l}$ Reagent C	50 $\mu\text{l}$ Reagent D
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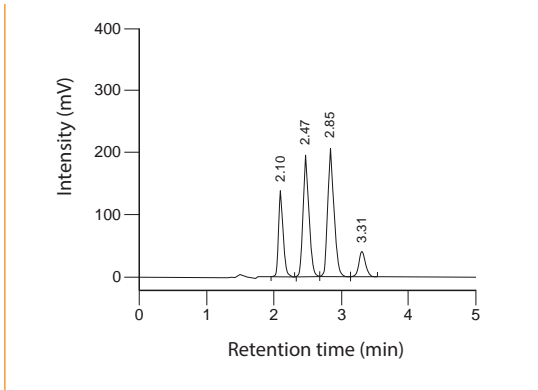
incubate (60 min, 60 °C)



### HPLC Analysis:

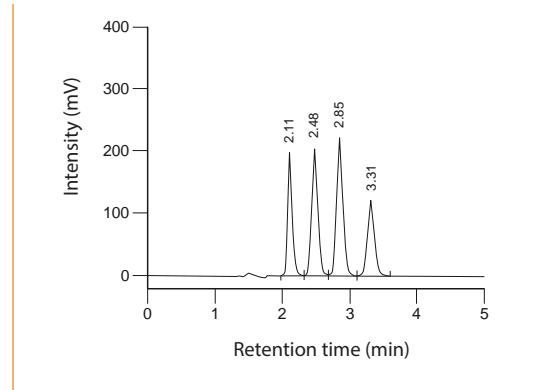
Inject 20 $\mu\text{l}$
-------------------------

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

# Porphyryns Differentiated in Urine

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

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



## Test Data

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

## HPLC Parameters

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

## Sample Preparation

### Addition of IS:

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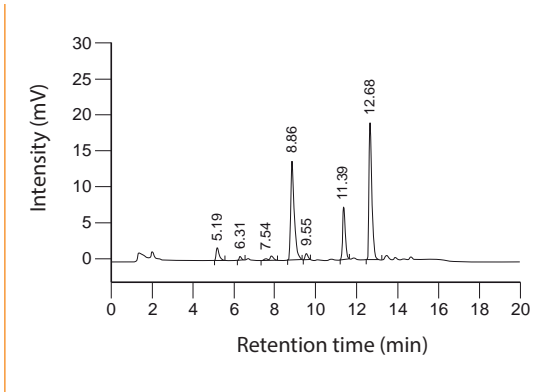
centrifuge

### HPLC Analysis:

Inject 20 µl of the supernatant

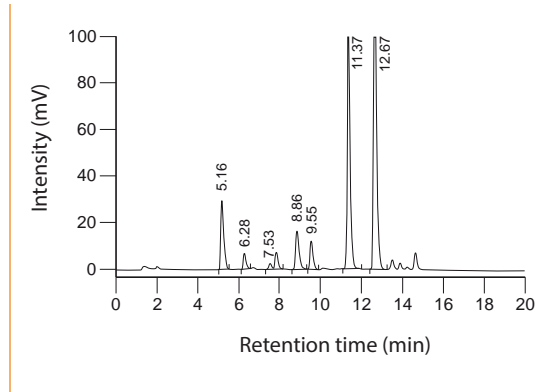


ClinChek® Urine Control, Level I



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

ClinChek® Urine Control, Level II



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

Ordering Information

Order No.	Description	Quantity
17000	ClinRep® Complete Kit for Porphyrins in Urine for 100 assays	1 pce.
<b>Kit Components (order no. 17000):</b>		
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.
<b>Start Accessories:</b>		
17030	Analytical Column with test chromatogram	1 pce.
17032	Guard Column Holder incl. 1 Guard Column	1 pce.
17033	Guard Column	5 pcs.
<b>Accessories:</b>		
FK5810	PEEK tubing (connection of prefilter and column)	1 pce.
FK5820	Stainless steel prefilter holder incl. 1 prefilter	1 pce.
FK5821	Replacement filter for stainless steel prefilter holder	10 pcs.
<b>ClinChek® Controls:</b>		
17080	Urine Control, lyophil., Level I	10 x 5 ml
17081	Urine Control, lyophil., Level II	10 x 5 ml
17082	Urine Control, lyophil., Level I, II	2 x 5 x 5 ml

## 1.1.4 Oxidative Stress

# Coenzyme Q10 in Whole Blood / Plasma / Serum

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

- Reliable sample preparation
- Reference materials with excellent stability available



## Test Data

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

## HPLC Parameters

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

## Sample Preparation

### Precipitation:

500 µl Precipitant P

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

mix

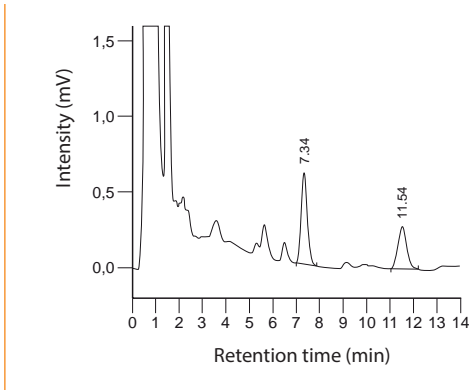
Add 400 µl Internal Standard IS

mix, centrifuge

### HPLC Analysis:

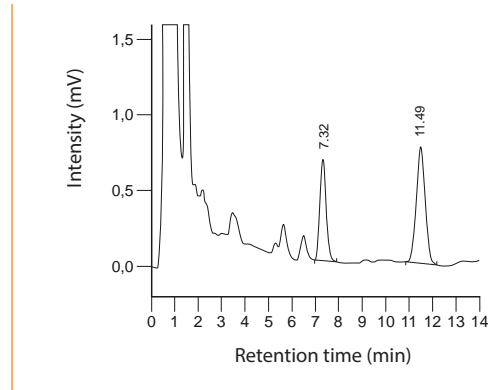
Inject 30 µl of the supernatant

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

## 1.1.4 Oxidative Stress

# Vitamin C in Plasma

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

- Quick sample preparation
- Injection interval: 5 min



## Test Data

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

## HPLC Parameters

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

## Sample Preparation

### Precipitation:

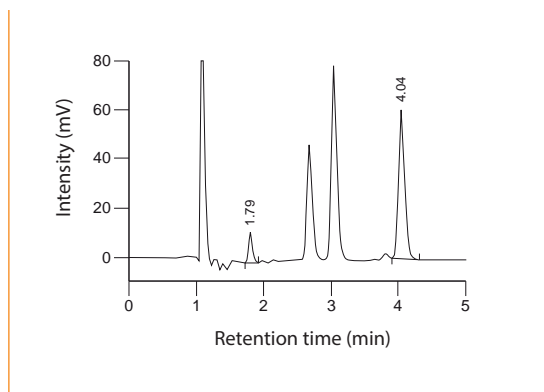
100 µl sample	100 µl Precipitant P (contains Internal Standard IS)
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1. incubate (10 min, + 4°C)
2. centrifuge

### HPLC Analysis:

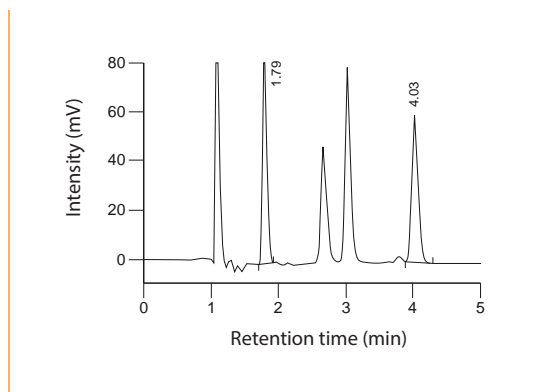
Inject 20 µl of the supernatant

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

## 1.1.5 Vitamin Status

# Vitamin A and E in Serum / Plasma

Vitamin A (retinol) and vitamin E ( $\alpha$ -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 $\mu$ l
Injection interval:	8 min
UV-Detector:	325 / 295 nm
HPLC-Thermostat:	30 °C

## Sample Preparation

### Extraction:

150 $\mu$ l plasma / serum	150 $\mu$ l Precipitant P (contains Internal Standard IS)
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centrifuge

### Stabilisation:

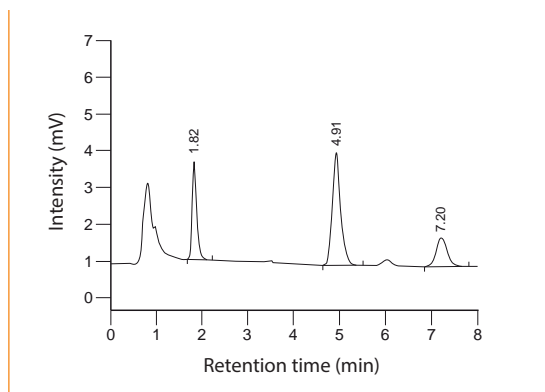
100 $\mu$ l supernatant	100 $\mu$ l Stabilising Reagent S
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centrifuge

### HPLC Analysis:

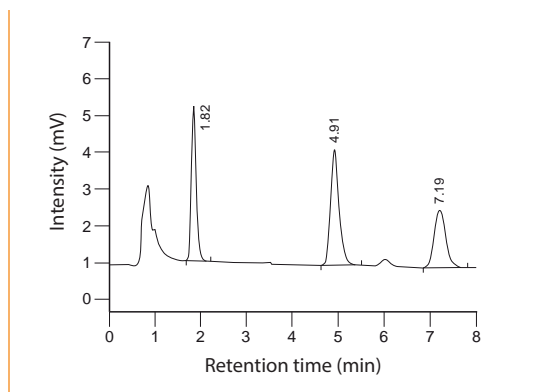
Inject 50 $\mu$ l of the supernatant
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ClinChek® Serum Control, Level I



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

## 1.1.5 Vitamin Status

# Vitamin A and E in Serum / Plasma by UHPLC

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

- Fast and simple
- Injection interval: 1.2 min



## Test Data

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

## UHPLC Parameters

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

## Sample Preparation

### Precipitation

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

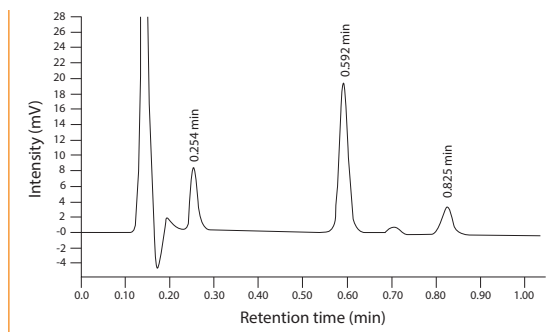


### UHPLC Analysis

Inject 5 µl of the supernatant

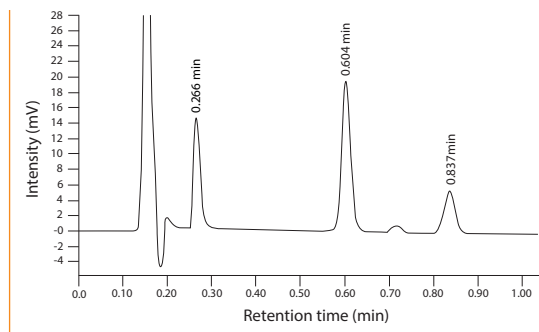


ClinChek® Serum Control, Level I



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

ClinChek® Serum Control, Level II



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

### Ordering Information

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

## 1.1.5 Vitamin Status

# Vitamin B1 in Whole Blood

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

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



## Test Data Determination as TPP

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

## HPLC Parameters

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

## Sample Preparation

### Extraction:

300 µl whole blood	500 µl Reagent A
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1. centrifuge
2. take off 400 µl supernatant

### Stabilisation:

Add 50 µl Reagent S

### Oxidation:

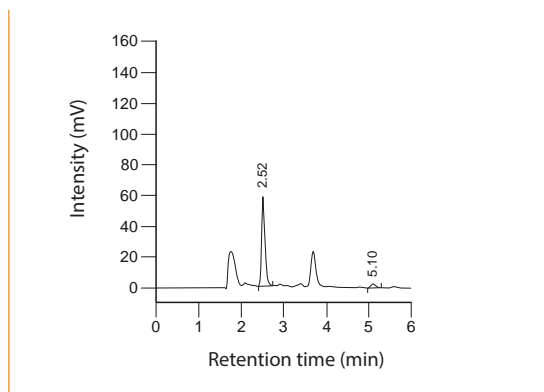
450 µl sample	50 µl Reagent C	100 µl Reagent D
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add 100 µl Reagent E

### HPLC Analysis:

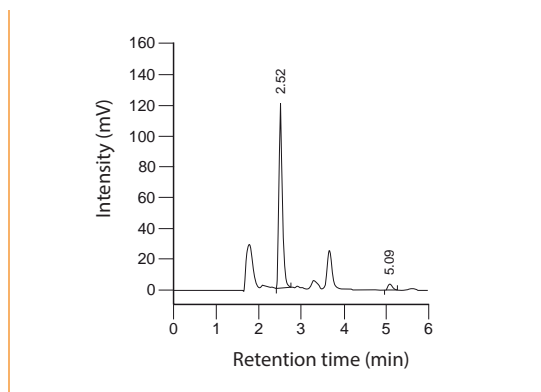
Inject 50 µl of the supernatant

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
<b>24000</b>	<b>ClinRep® Complete Kit for Vitamin B1 in Whole Blood for 100 assays</b>	<b>1 pce.</b>
<b>Kit Components (order no. 24000):</b>		
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.
<b>Start Accessories:</b>		
27030	Analytical Column with test chromatogram	1 pce.
27032	Guard Column Holder incl. 1 Guard Column	1 pce.
<b>Accessories:</b>		
27033	Guard Columns	5 pcs.
FK2000	Peristaltic pump (flow rate 0.2 ml/min)	1 pce.
FK2001	Replacement tubings for peristaltic pump	2 pcs.
FK5121	T-Union (PEEK), 1/16"	1 pce.
FK5810	PEEK-tubing (connection of prefilter and column)	1 pce.
FK5820	Stainless steel prefilter holder incl. 1 prefilter	1 pce.
FK5821	Replacement filter for stainless steel prefilter holder	10 pcs.
<b>ClinChek® Controls:</b>		
8874	Whole Blood Control, lyophil., Level I	10 x 2 ml
8875	Whole Blood Control, lyophil., Level II	10 x 2 ml
8876	Whole Blood Control, lyophil., Level I, II	2 x 5 x 2 ml

## 1.1.5 Vitamin Status

# Vitamin B2 in Whole Blood

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

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



## Test Data Determination as FAD

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

## HPLC Parameters

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

## Sample Preparation

### Extraction:

200 µl whole blood	300 µl Precipitant P
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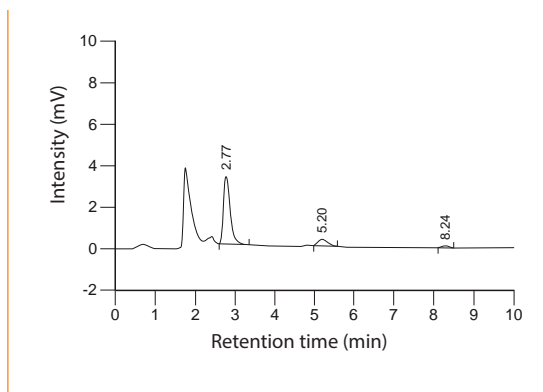
1. add 500 µl Stabilising Reagent S
2. centrifuge

### HPLC Analysis:

Inject 50 µl of the supernatant

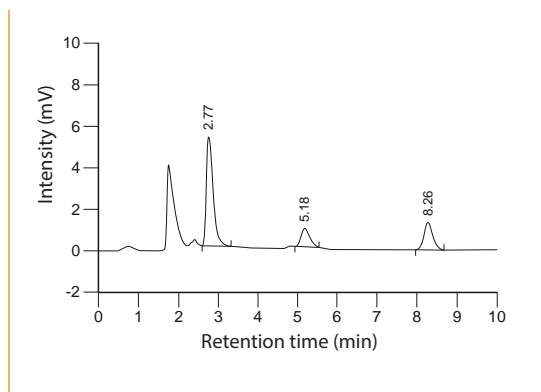
## 1.1.5 Vitamin Status

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

## 1.1.5 Vitamin Status

# Vitamin B6 in Plasma / Whole Blood

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

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



## Test Data Determination from plasma / from whole blood

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

## HPLC Parameters

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

## Sample Preparation

### Extraction:

100 µl sample

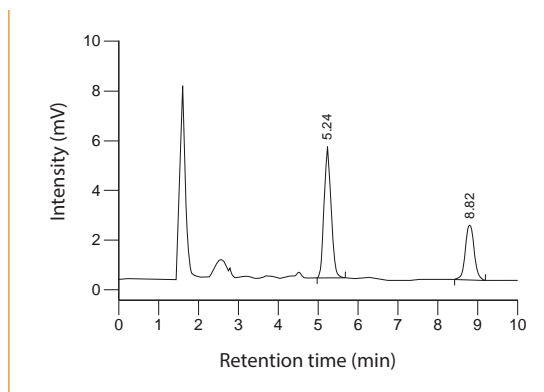
100 µl Precipitant P

centrifuge

### HPLC Analysis:

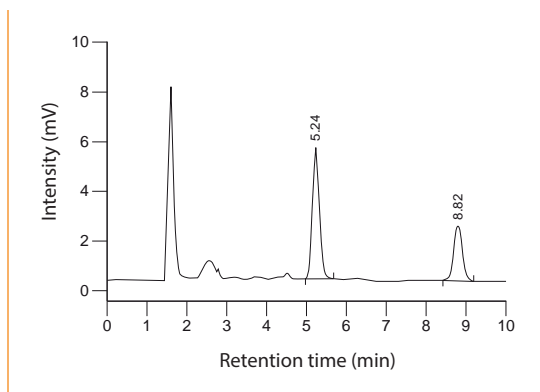
Inject 50 µl of the supernatant

ClinChek® Whole Blood Control, Level I



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

ClinChek® Whole Blood Control, Level II



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

### Ordering Information

Order No.	Description	Quantity
<b>26000</b>	<b>ClinRep® Complete Kit for Vitamin B6 in Plasma / Whole Blood for 100 assays</b>	<b>1 pce.</b>
<b>Kit Components (order no. 26000):</b>		
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.
<b>Optional Components:</b>		
24513	Whole Blood Calibrator, lyophil.	5 x 2 ml
<b>Start Accessories:</b>		
27030	Analytical Column with test chromatogram	1 pce.
27032	Guard Column Holder incl. 1 Guard Column	1 pce.
<b>Accessories:</b>		
27033	Guard Columns	5 pcs.
FK2000	Peristaltic pump (flow rate 0.2 ml/min)	1 pce.
FK2001	Replacement tubings for peristaltic pump	2 pcs.
FK5121	T-Union (PEEK), 1/16"	1 pce.
FK5810	PEEK-tubing (connection of prefilter and column)	1 pce.
FK5820	Stainless steel prefilter holder incl. 1 prefilter	1 pce.
FK5821	Replacement filter for stainless steel prefilter holder	10 pcs.
<b>ClinChek® Controls:</b>		
8870	Serum Control, lyophil., Level I	10 x 5 ml
8871	Serum Control, lyophil., Level II	10 x 5 ml
8872	Serum Control, lyophil., Level III	10 x 5 ml
8873	Serum Control, lyophil., Level I, II, III	3 x 3 x 5 ml
8874	Whole Blood Control, lyophil., Level I	10 x 2 ml
8875	Whole Blood Control, lyophil., Level II	10 x 2 ml
8876	Whole Blood Control, lyophil., Level I, II	2 x 5 x 2 ml

## 1.1.5 Vitamin Status

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

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

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



### Test Data

Test data are available on request.

HPLC Parameters	Vitamin B1
Pump (Mobile Phase A + B):	flow rate 1 ml/min ratio A : B = 93 : 7
Pump (Reagent N):	flow rate 0.1 ml/min
Injection volume:	50 µl
Injection interval:	6 min
HPLC-Thermostat:	35 °C
Detector (exc. / em.):	376 nm / 435 nm
Retention times:	
TPP	approx. 2.5 min

HPLC Parameters	Vitamin B2
Pump (Mobile Phase A + B):	flow rate 1 ml/min ratio A : B = 80 : 20
Injection volume:	50 µl
Injection interval:	10 min
HPLC-Thermostat:	40 °C
Detector (exc. / em.):	450 nm / 530 nm
Retention times:	
FAD	approx. 2.8 min

HPLC Parameters	Vitamin B6
Pump (Mobile Phase A + B):	flow rate 1 ml/min ratio A : B = 100 : 0
Pump (Reagent N):	flow rate 0.2 ml/min
Injection volume:	50 µl
Injection interval:	10 min
HPLC-Thermostat:	25 °C
Detector (exc. / em.):	370 nm / 470 nm
Retention times:	
PLP	approx. 5.2 min



## Sample Preparation

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

## Chromatograms

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

## Ordering Information

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

## A: Chromatography

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

## B: Sample Preparation

Order No.	Description	Quantity	
<b>27001</b>	<b>ClinRep® Sample Preparation Kit for Vitamin B1 in Whole Blood for 100 assays</b>	<b>1 pce. *</b>	<b>Mobile phase not included</b>
<b>Kit Components (order no. 27001):</b>			
	Identical with order no. 24000 (s. page 59), but without mobile phase		
<b>27002</b>	<b>ClinRep® Sample Preparation Kit for Vitamin B2 in Whole Blood for 100 assays</b>	<b>1 pce. *</b>	
<b>Kit Components (order no. 27002):</b>			
	Identical with order no. 25000 (s. page 61), but without mobile phase		
<b>27006</b>	<b>ClinRep® Sample Preparation Kit for Vitamin B6 in Plasma and Whole Blood for 100 assays</b>	<b>1 pce. *</b>	
<b>Kit Components (order no. 27006):</b>			
	Identical with order no. 26000 (s. page 63), but without mobile phase		
		*	

## 1.1.5 Vitamin Status

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

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

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



## Test Data

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

## HPLC Parameters

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

## Sample Preparation

### Precipitation:

500 µl Precipitant P

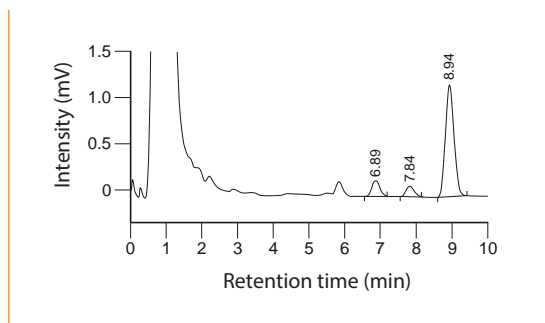
1. Add 400 µl sample
2. Add 400 µl Internal Standard IS

mix, centrifuge

### HPLC Analysis:

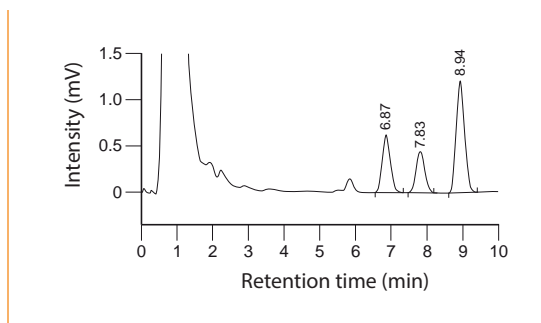
Inject 50 µl of the supernatant

ClinChek® Serum Control, Level I



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

ClinChek® Serum Control, Level II



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

### Ordering Information

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

## 1.1.5 Vitamin Status

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

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

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



## Test Data

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

## UHPLC Parameters

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

## Sample Preparation

### Precipitation:

500 µl Precipitant P

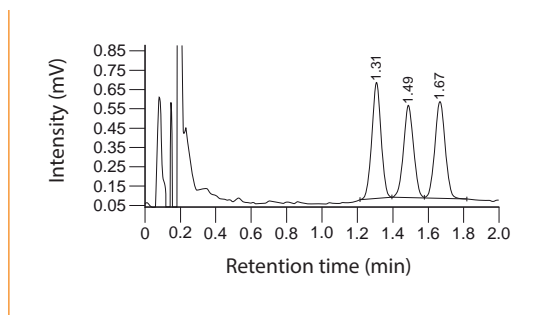
1. Add 400 µl sample
2. Add 400 µl Internal Standard IS

mix, centrifuge

### UHPLC Analysis:

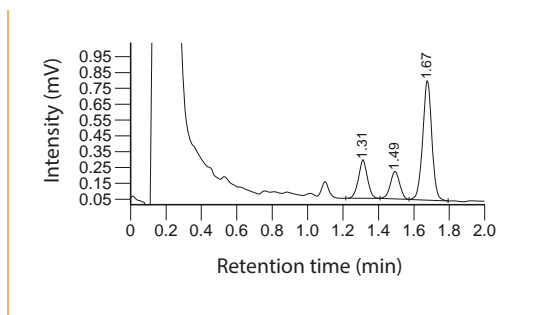
Inject 5 µl of the supernatant

ClinTest® Test Solution



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

ClinCal® Serum Calibrator



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

### Ordering Information

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

## 1.2.1 Antiarrhythmics

# Amiodarone in Plasma

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

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

## Test Data

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

## HPLC Parameters

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

## Sample Preparation

### Extraction:

100 µl sample

150 µl Precipitant P  
(contains Internal Standard IS)

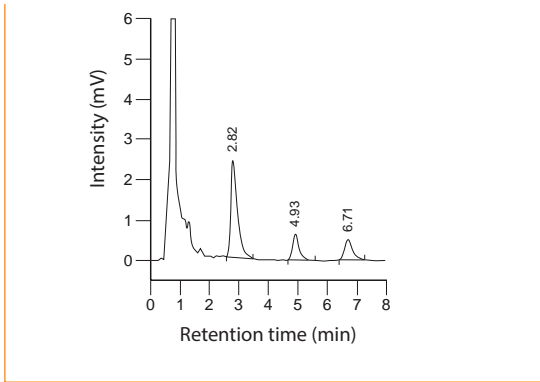
centrifuge

### HPLC Analysis:

Inject 20 µl of the supernatant

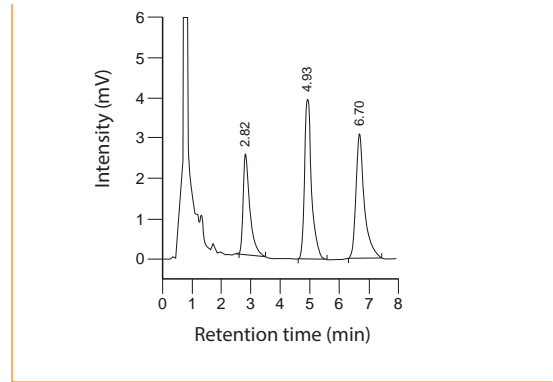


ClinChek® Serum Control, Level I



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

## 1.2.2 Antiepileptic Drugs

# Antiepileptics in Serum/ Plasma, *advanced*

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

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



## Test Data

The test data are available on request.

## HPLC Parameters

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

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

## Sample Preparation

### Extraction:

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

centrifuge



### Dilution:

150 µl supernatant	250 µl Diluting Solution D
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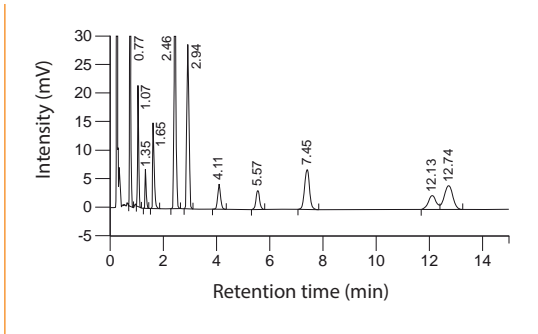


### HPLC Analysis:

Inject 10 µl of the diluted supernatant
---

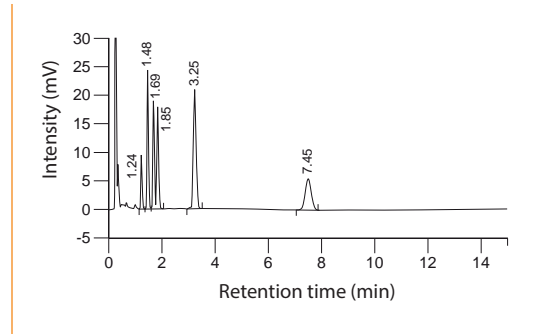


ClinChek® Serum Control, Level II (order no. 14081)



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

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



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

### Ordering Information

Order No.	Description	Quantity
<b>14000</b>	<b>ClinRep® Complete Kit, advanced, for Antiepileptics in Serum / Plasma for 100 assays</b>	<b>1 pce.</b>
<b>Kit Components (order no. 14000):</b>		
14010	Mobile Phase	1000 ml
14011	Standard Solution Antiepileptics 3	3 ml
14111	Standard Solution Antiepileptics 4	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.
<b>Optional Components:</b>		
14113	Serum Calibrator Antiepileptics 4, lyophil.	3 ml
<b>Start Accessories:</b>		
14030	Analytical Column with test chromatogram	1 pce.
<b>Accessories:</b>		
FK5810	PEEK tubing (connection of prefilter and column)	1 pce.
FK5820	Stainless steel prefilter holder incl. 1 prefilter	1 pce.
FK5821	Replacement filter for stainless steel prefilter holder	10 pcs.
<b>ClinChek® Controls:</b>		
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

## 1.2.2 Antiepileptic Drugs

# Antiepileptics in Serum/ Plasma with UHPLC

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

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

## Test Data

The test data are available on request.

## UHPLC Parameters

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

## Sample Preparation

### Precipitation:

100 µl sample	200 µl Precipitant P (contains Internal Standard)
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centrifuge



### Dilution:

150 µl supernatant	250 µl Diluting Solution D
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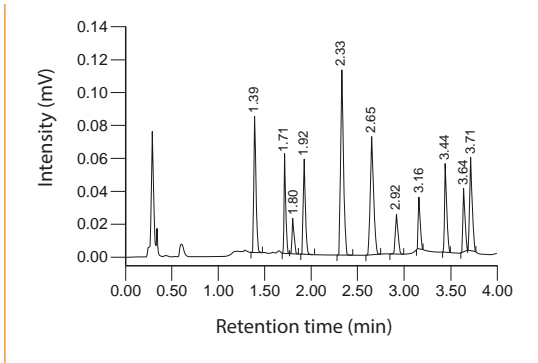


### UHPLC Analysis:

Inject 2 µl of the diluted supernatant
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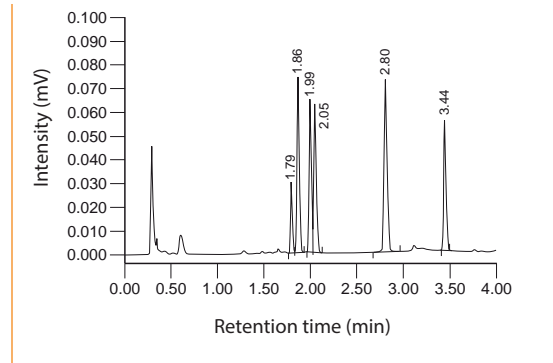


ClinChek® Serum Control, Level II (order no. 14081)



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

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



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

### Ordering Information

Order No.	Description	Quantity
<b>14100</b>	<b>ClinRep® Complete Kit for Antiepileptics in Serum / Plasma for 100 assays</b>	<b>1 pce.</b>
<b>Kit Components (order no. 14100):</b>		
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.
<b>Optional Components:</b>		
14111	Standard Solution Antiepileptics 4	3 ml
14113	Serum Calibrator Antiepileptics 4, lyophil.	3 ml
<b>Start Accessories:</b>		
14130	Analytical Column with test chromatogram	1 pce.
<b>ClinChek® Controls:</b>		
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

## 1.2.2 Antiepileptic Drugs

# Levetiracetam (Keppra®) in Serum and Plasma

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

- One analytical column for levetiracetam and further 16 AEDs



## Test Data

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

## HPLC Parameters

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

## Sample Preparation

### Extraction:

Apply (conditioned\* sample preparation column):

Sample (100 µl)	Internal Standard IS (100 µl)
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wash with

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



### Elution:

Apply Eluting Reagent E  
(1 ml / 500 µl)



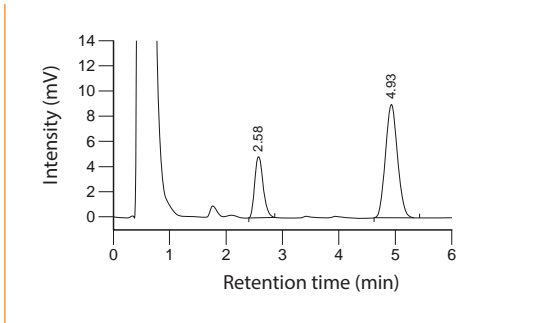
### HPLC Analysis:

Inject 20 µl

\* Conditioning with Conditioning Reagent C and Washing Solution W1

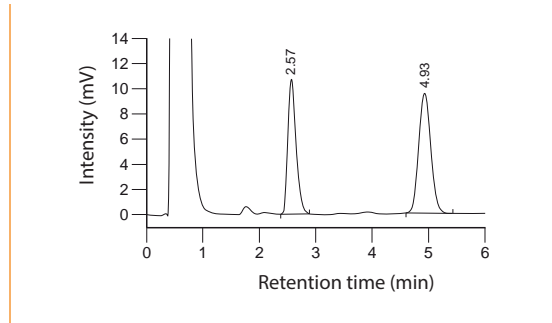
## 1.2.2 Antiepileptic Drugs

ClinChek® Serum Control, Level I



Levetiracetam: 2.58 min, IS: 4.93 min

ClinChek® Serum Control, Level II



Levetiracetam: 2.57 min, IS: 4.93 min

### Ordering Information

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

## 1.2.3 Immunosuppressants

# Mycophenolic Acid in Plasma

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

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



## Test Data

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

## HPLC Parameters

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

## Sample Preparation

### Extraction:

100 µl plasma	20 µl Internal Standard IS	200 µl Precipitant P
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centrifuge

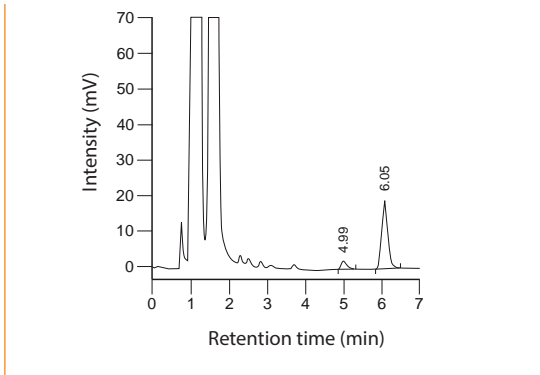


### HPLC Analysis:

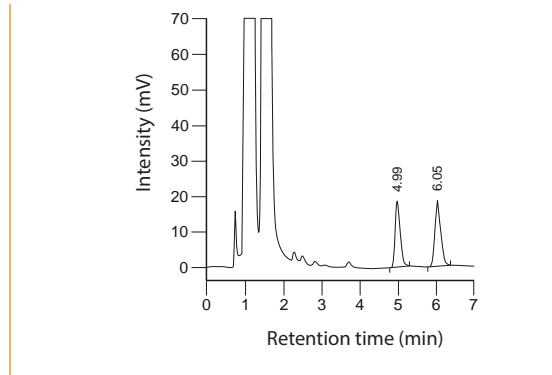
Inject 50 µl of the supernatant
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## 1.2.3 Immunosuppressants

ClinChek® Plasma Control, Level I:



ClinChek® Plasma Control, Level II:



Mycophenolic acid: 4.99 min, IS: 6.05 min

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.
<b>Kit Components (order no. 29000):</b>		
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.
<b>Start Accessories:</b>		
29030	Analytical Column with test chromatogram	1 pce.
<b>Accessories:</b>		
FK5810	PEEK-tubing (connection of prefilter and column)	1 pce.
FK5820	Stainless steel prefilter holder incl. 1 prefilter	1 pce.
FK5821	Replacement filter for stainless steel prefilter holder	10 pcs.
<b>ClinChek® Controls:</b>		
29083	Plasma Control, lyophil., Level I, II, III	3 x 3 x 3 ml

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

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

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



## Test Data

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

## HPLC Parameters

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

**B:** Determination of Plp, Rsp

Isocratic pump 1

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

Isocratic pump 2

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

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

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

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

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

HPLC-thermostat: 30 °C

## Sample Preparation

### Extraction:

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

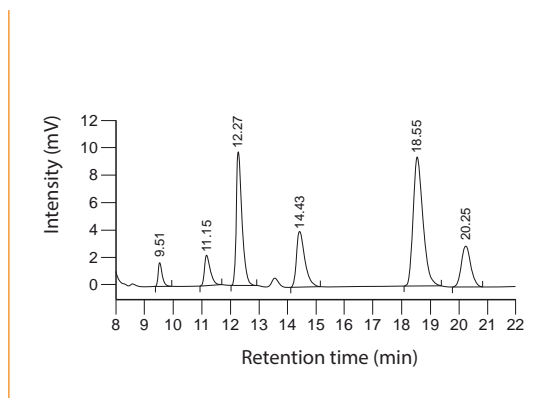
centrifuge

### on-line Analysis:

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

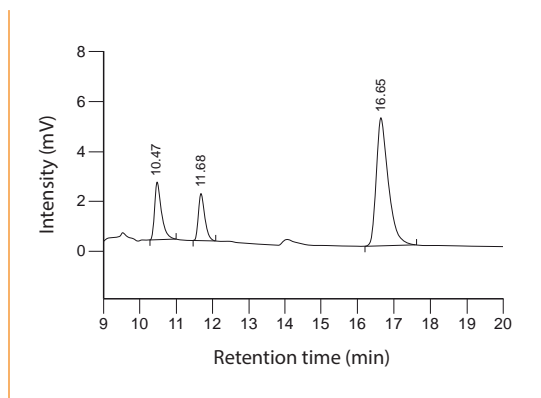


Chromatogram of the plasma calibrator, order no. 40013  
(+ 20 µl Internal Standard IS per ml sample, order no. 40012)



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

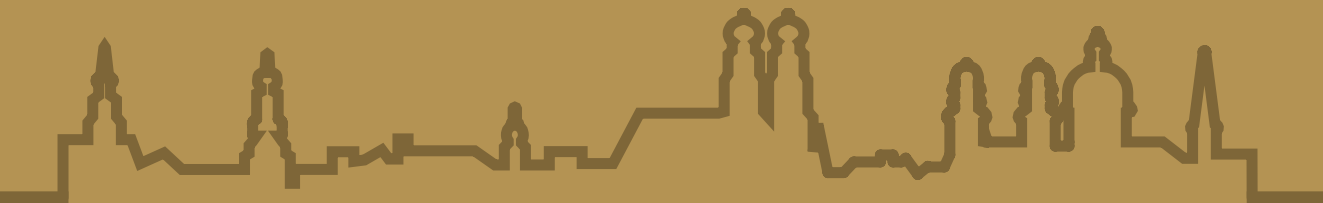
Chromatogram of the plasma calibrator, order no. 40113  
(+ 10 µl Internal Standard IS per ml sample, order no. 40012)



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

### Ordering Information

Order No.	Description	Quantity
<b>40000</b>	<b>ClinRep® Complete Kit for Atypical Neuroleptics in Plasma / Serum for 100 assays</b>	<b>1 pce.</b>
<b>Kit Components (order no. 40000):</b>		
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.
<b>Optional Components:</b>		
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
<b>Start Accessories:</b>		
40030	Analytical Column with test chromatogram	1 pce.
40031	SPE-Column	1 pce.
40032	Guard Column Holder incl. 1 Guard Column	1 pce.
40033	Guard Columns	5 pcs.
FK7400	Inline-Filter (stainless steel sieve, free of dead volume)	1 pce.
<b>Refill Service:</b>		
40034	SPE-Column, refill (original column needs to be returned)	1 pce.
<b>Accessories:</b>		
FK1102	Switching valve, Sykam (6-port/3-channel) incl. electr. drive, PEEK	1 pce.
FK7340	Sealings and sieves for order no. FK7400	4 pcs. each
<b>ClinChek® Controls:</b>		
40082	Plasma Control, lyophil., Level I, II	2 x 5 x 3 ml
40182	Plasma Control, lyophil., for Risperidone and Paliperidone, Level I, II	2 x 5 x 5 ml



Authorised Representative:



**Ingeniería Analítica**  
Chromatography & Spectrometry

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