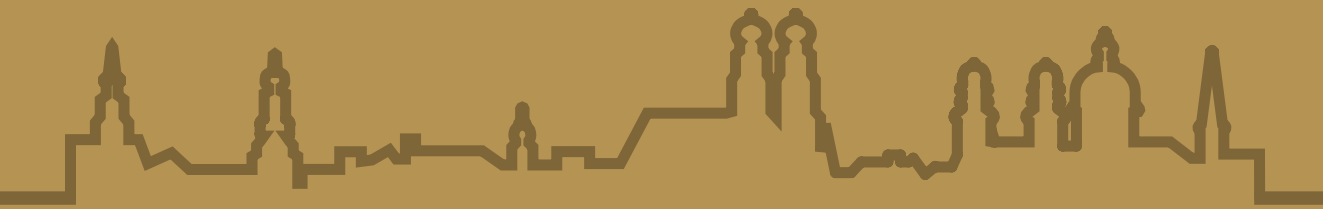


+RECIPE

HPLC & LC-MS/MS

IVD Complete Kits



40
Years RECIPE

Product Catalogue I
2022/2023

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2. Photometric Complete Kits

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

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

5-Aminolevulinic Acid / Porphobilinogen in Urine

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

- Easy handling
- Reliable test results



Test Data

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

Sample Preparation

Extraction:

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

wash (3 x 10 ml HPLC water)

Separate the double column

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

A: Sample Preparation for 5-ALA

Elution:

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

collect the eluate

Derivatisation:

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

Analysis:

Photometric measurement

B: Sample Preparation for PBG

Elution:

Elute with 4.0 ml Reagent D

collect the eluate

Derivatisation:

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

Analysis:

Photometric measurement

2.1.1 Porphyria, Lead Intoxication

Ordering Information

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

Porphobilinogen in Urine

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

- Easy handling
- Reliable test results

Test Data

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

Sample Preparation

Extraction:

Apply 0.5 ml urine to a conditioned
PBG column

wash (3 x 10 ml HPLC water)



Elution:

Elute with 4.0 ml Reagent D

collect the eluate



Derivatisation:

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



Analysis:

Photometric measurement



2.1.1 Porphyria, Lead Intoxication

Ordering Information

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

2.1.1 Porphyria, Lead Intoxication

Total Porphyrins in Urine

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

- Easy handling
- Reliable test results

Test Data

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

Sample Preparation

Extraction:

Apply 1.0 ml urine to a conditioned sample preparation column

wash (10 ml HPLC water)



Elution:

Elute with 2.0 ml Eluting Reagent E

collect the eluate



Analysis:

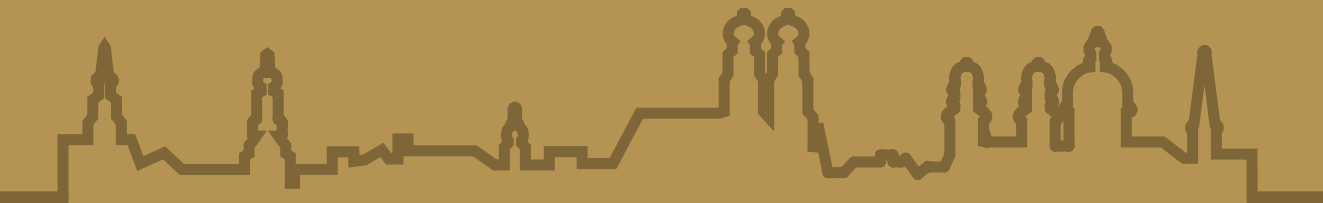
Photometric measurement



2.1.1 Porphyria, Lead Intoxication

Ordering Information

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



Authorised Representative:



Ingeniería Analítica
Chromatography & Spectrometry

Last revision May 2022

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