

Deutsche Akkreditierungsstelle GmbH

Annex to the Accreditation Certificate D-K-15117-02-00
according to DIN EN ISO/IEC 17025:2018 and
DIN EN ISO 15195:2004

Valid from: 22.11.2019

Date of issue: 22.11.2019

Holder of certificate:

**Stiftung für Pathobiochemie und Molekulare Diagnostik
Referenzinstitut für Bioanalytik
Kalibrierlaboratorium II
An der Medizinischen Hochschule Hannover
Institut für Klinische Chemie
Carl-Neuberg-Straße 1, 30625 Hannover**

Calibration in the fields:

Medical reference measurement laboratories

- **Amount of substance concentration**
- **Catalytic activity concentration**

Abbreviations used: see last page

Annex to the accreditation certificate D-K-15117-02-00

Permanent laboratory

Measured quantity / Calibration item	Range	Measurement conditions / procedure	Best measurement capability ¹⁾	Remarks
Amount of substance concentration Glucose	0.5 mmol/L to 25 mmol/L	ID-GC-MS, <i>in house</i> procedure, MHH-Hannover, date: 10/07/2018	1.0 %	System ^{a)} : Serum, plasma, urine, blood, liquor
Potassium	0.75 mmol/L to 75 mmol/L	ICP-OES, Metrologia 2018;55:245-253	1.5 %	System ^{a)} : Serum, plasma, urine
Lithium	0.05 mmol/L to 5.0 mmol/L		1.5 %	
Sodium	5.0 mmol/L to 200 mmol/L		1.5 %	
Calcium	0.4 mmol/L to 8.0 mmol/L		1.5 %	
Magnesium	0.1 mmol/L to 4.0 mmol/L		1.5 %	
Chloride	50 mmol/L to 290 mmol/L	Coulometric, <i>in house</i> procedure, MHH-Hannover, date: 10/07/2018	1.5 %	
Catalytic activity concentration Alanine aminotransferase (ALT)	0.072 μ kat/L to 4.75 μ kat/L (4.3 U/L) (285 U/L)	Kinetic photometric measurement of absorbance, IFCC reference measurement procedure (37°C), Clin Chem Lab Med 2002;40:718–724	2.2 %	System ^{a)} : Serum, plasma
Alkaline phosphatase (ALP)	0.092 μ kat/L to 11.3 μ kat/L (5.5 U/L) (680 U/L)	Kinetic photometric measurement of absorbance, IFCC reference measurement procedure (37°C), Clin Chem Lab Med 2011;49:1439–1446	2.8 %	
α -Amylase (AMY)	0.058 μ kat/L to 12.0 μ kat/L (3.5 U/L) (720 U/L)	Kinetic photometric measurement of absorbance, IFCC reference measurement procedure (37°C), Clin Chem Lab Med 2006;44:1146–1155	2.7 %	
Aspartate aminotransferase (AST)	0.040 μ kat/L to 4.17 μ kat/L (2.4 U/L) (250 U/L)	Kinetic photometric measurement of absorbance,	2.2 %	

¹⁾ The expanded uncertainties according to EA-4/02 M:2013 are part of CMC and are the best measurement uncertainties within accreditation. They have a coverage probability of approximately 95 % and have a coverage factor of $k = 2$ unless stated otherwise. Uncertainties without unit are relative uncertainties referring to the measurement value unless stated otherwise.

Annex to the accreditation certificate D-K-15117-02-00

Measured quantity / Calibration item	Range	Measurement conditions / procedure	Best measurement capability ¹⁾	Remarks
Creatine kinase (CK)		IFCC reference measurement procedure (37°C), Clin Chem Lab Med 2002; 40:725–733		
	0.155 µkat/L to 24.33 µkat/L (9.3 U/L) (1460 U/L)	Kinetic photometric measurement of absorbance, IFCC reference measurement procedure (37°C), Clin Chem Lab Med 2002; 40:635–642	2.4 %	
	γ-Glutamyltransferase (GGT)	0.032 µkat/L to 4.58 µkat/L (1.9 U/L) (275 U/L)	Kinetic photometric measurement of absorbance, IFCC reference measurement procedure (37°C), Clin Chem Lab Med 2002; 40:734–738	2.2 %
Lactate dehydrogenase (LDH)	0.145 µkat/L to 10.0 µkat/L (8.7 U/L) (600 U/L)	Kinetic photometric measurement of absorbance, IFCC reference measurement procedure (37°C), Clin Chem Lab Med 2002; 40:643–648	2.2 %	
Bilirubin	5 µmol/L to 525 µmol/L	Spectrophotometry Clin Chim Acta 2018;481:115-120	2.2 %	System ^{a)} : Serum, Plasma
Hämoglobin	20 g/L to 300 g/L	Spectrophotometry, HiCN method DIN 58931:2010-08, Consensus optimization (MHH-Hannover, date: 26/04/2018)	1.1 %	System ^{a)} : Blood

System ^{a)} These systems are built up of native material or processed material similar to system material (lyophilised or liquid)

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Annex to the accreditation certificate D-K-15117-02-00

Abbreviations used:

CMC	Calibration and measurement capabilities (Kalibrier- und Messmöglichkeiten)
DIN	Deutsches Institut für Normung e.V.
ICP-OES	Inductively coupled plasma optical emission spectrometry
ID-GC-MS	Online-combination of gas chromatography / isotope dilution mass spectrometry

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