

Deutsche Akkreditierungsstelle GmbH

Annex to the Accreditation Certificate D-K-15027-01-00 according to DIN EN ISO/IEC 17025:2018 and DIN EN ISO 15195:2004

Valid from: 07.09.2020

Date of issue: 07.09.2020

Holder of certificate:

**INSTAND e. V. Gesellschaft zur Förderung der Qualitätssicherung in medizinischen
Laboratorien e. V.
Uwierstraße 20, 40223 Düsseldorf**

Calibration in the fields:

Medical reference measurement laboratories

- Amount of substance concentration
- Catalytic activity concentration
- Mass concentration

Abbreviations used: see last page

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Permanent Laboratory

Calibration and Measurement Capabilities (CMC)

Measured quantity / Calibration item	Range	Measurement conditions / procedure	Expanded uncertainty of measurement ¹⁾	Remarks
Amount-of-substance concentration of calcium in plasma, serum or material similar to plasma or serum	0.5 mmol/L to 8 mmol/L	High resolution inductively-coupled-plasma-isotope dilution mass spectrometry (ICP-ID/SMS) Clin. Lab., 2013, 59, 1017-1029.	1.0 %	
Amount-of-substance concentration of chloride in plasma, serum or material similar to plasma or serum	50 mmol/L to 150 mmol/L		1.0 %	
Amount-of-substance concentration of potassium in plasma, serum or material similar to plasma or serum	1 mmol/L to 10 mmol/L		1.0 %	
Amount-of-substance concentration of potassium in urine	1 mmol/L to 200 mmol/L		1.0 %	
Amount-of-substance concentration of lithium in plasma, serum or material similar to plasma or serum	0.1 mmol/L to 5 mmol/L		1.0 %	
Amount-of-substance concentration of magnesium in plasma, serum or material similar to plasma or serum	0.1 mmol/L to 5 mmol/L		1.0 %	
Amount-of-substance concentration of sodium in plasma, serum or material similar to plasma or serum	70 mmol/L to 200 mmol/L		High resolution inductively-coupled-plasma mass spectrometry (ICP-/SMS) Clin. Lab., 2013, 59, 1017 - 1029.	1.0 %
Amount-of-substance concentration of sodium in urine	20 mmol/L to 300 mmol/L	1.0 %		

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.

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Measured quantity / Calibration item	Range	Measurement conditions / procedure	Expanded uncertainty of measurement ¹⁾	Remarks
Catalytic activity concentration of ALT in serum or material similar to serum	0.33 µkat/L (20 U/L) to 6.67 µkat/L (400 U/L)	Kinetic spectrophotometry according to IFCC (37°C) Clin. Chem. Lab. Med., 2002, 40, 718-724.	2,5 %	
Catalytic activity concentration of AST in serum or material similar to serum	0.33 µkat/L (20 U/L) to 6.67 µkat/L (400 U/L)	Kinetic spectrophotometry according to IFCC (37°C) Clin. Chem. Lab. Med., 2002, 40, 725-733.	2,5 %	
Catalytic activity concentration of CK in serum or material similar to serum	0.8 µkat/L (48 U/L) to 24 µkat/L (1440 U/L)	Kinetic spectrophotometry according to IFCC (37°C) Clin. Chem. Lab. Med., 2002, 40, 635-642.	2,5 %	
Catalytic activity concentration of GGT in serum or material similar to serum	0.33 µkat/L (20 U/L) to 5 µkat/L (300 U/L)	Kinetic spectrophotometry according to IFCC (37°C) Clin. Chem. Lab. Med., 2002, 40, 734-738.	2.5 %	
Catalytic activity concentration of LDH in serum or material similar to serum	1 µkat/L (60 U/L) to 12 µkat/L (720 U/L)	Kinetic spectrophotometry according to IFCC (37°C) Clin. Chem. Lab. Med., 2002, 40, 643-648.	2.5 %	
Amount-of-substance concentration of cholesterol in serum or material similar to serum	1 mmol/L to 10 mmol/L	Gas-chromatography-isotope dilution mass spectrometry (GC-IDMS) Clin. Chem., 1993, 39, 993-1000. Clin. Chem., 1993, 39, 1001-1006.	1.0 %	
Amount-of-substance concentration of creatinine in serum or material similar to serum	25 µmol/L to 2000 µmol/L		1.0 %	
Amount-of-substance concentration of creatinine in urine	0,05 mmol/L to 40 mmol/L		1.0 %	
Amount-of-substance concentration of glucose in serum or material similar to serum	1 mmol/L to 60 mmol/L		1.0 %	
Amount-of-substance concentration of glucose in liquor or material similar to liquor	0,5 mmol/L to 60 mmol/L		1.0 %	

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Measured quantity / Calibration item	Range	Measurement conditions / procedure	Expanded uncertainty of measurement ¹⁾	Remarks
Amount-of-substance concentration of glucose in urine	0,5 mmol/L to 60 mmol/L	Gas-chromatography-isotope dilution mass spectrometry (GC-IDMS) Clin. Chem., 1993, 39, 993-1000. Clin. Chem., 1993, 39, 1001-1006.	1.0 %	
Amount-of-substance concentration of uric acid in serum or material similar to serum	50 µmol/L to 1000 µmol/L		1.0 %	
Amount-of-substance concentration of uric acid in urine	20 µmol/L to 2500 µmol/L		1.0 %	
Amount-of-substance concentration of urea in serum or material similar to serum	0.5 mmol/L to 50 mmol/L	Gas-chromatography-isotope dilution mass spectrometry (GC-IDMS) Clin. Chem., 1999, 45, 1523-1529.	1.0 %	
Amount-of-substance concentration of urea in urine	0.5 mmol/L to 500 mmol/L		1.0 %	
Amount-of-substance concentration of total glycerol in serum or material similar to serum	0.5 mmol/L to 6.0 mmol/L	Gas-chromatography-isotope dilution mass spectrometry (GC-IDMS) Eur. J. Clin. Chem. Clin. Biochem., 1996, 34, 853-860.	1.0 %	
Amount-of-substance concentration of cortisol in serum or material similar to serum	30 nmol/L to 2000 nmol/L	Gas-chromatography-isotope dilution mass spectrometry (GC-IDMS) Anal. Biochem., 1996, 234, 204-209.	1.0 %	
Amount-of-substance concentration of 17β-estradiol in serum or material similar to serum	37 pmol/L to 2500 pmol/L	Gas-chromatography-isotope dilution mass spectrometry (GC-IDMS) J. Clin. Chem. Clin. Biochem., 1984, 22, 551-557.	1.0 %	
Amount-of-substance concentration of progesterone in serum or material similar to serum	0,5 nmol/L to 150 nmol/L	Gas-chromatography-isotope dilution mass spectrometry (GC-IDMS) Anal. Chem., 1994, 66, 4116-4119.	1.0 %	
Amount-of-substance concentration of testosterone in serum or material similar to serum	0.7 nmol/L to 70 nmol/L		1.5 %	

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Amount-of-substance concentration of thyroxine in serum or material similar to serum	6.4 nmol/L to 300 nmol/L	Gas-chromatography-isotope dilution mass spectrometry (GC-IDMS) Biol. Mass Spectrom., 1994, 23, 475-482.	1.0 %	
Mass concentration of total protein in serum or material similar to serum	25 g/L to 130 g/L	Spectrophotometry Clin. Chem., 1981, 27, 1642-1650.	1.5 %	
Mass concentration of hämoglobin in blood, material similar to blood or lysate	20 g/L to 200 g/L	DIN 58931:2010 HiCN-Methode.	1,1 %	
Amount-of-substance fraction of HbA1c in whole blood, material similar to whole blood or blood lysate	29 mmol/mol to 150 mmol/mol	High pressure liquid chromatography mass spectrometry (LC-MS/MS) according to IFCC Clin. Chem., 2008, 54, 1018-1022.	1.5 %	
Amount-of-substance concentration of digitoxin in serum or material similar to serum	1 nmol/L to 100 nmol/L	High pressure liquid chromatography isotope dilution mass spectrometry (LC-IDMS) Clin. Lab., 2006, 52, 37-42.	2.5 %	
Amount-of-substance concentration of digoxin in serum or material similar to serum	0,2 nmol/L to 20 nmol/L		1.0 %	
Amount-of-substance concentration of theophyllin in serum or material similar to serum	5 µmol/L to 500 µmol/L	Gas-chromatography-isotope dilution mass spectrometry (GC-IDMS) Clin. Lab., 2002, 48, 535-540.	1.0 %	

Abbreviations used:

CMC Calibration and measurement capabilities (Kalibrier- und Messmöglichkeiten)

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.