DAkkS
Deutsche
Akkreditierungsstelle

Deutsche Akkreditierungsstelle GmbH

Entrusted according to Section 8 subsection 1 AkkStelleG in connection with Section 1 subsection 1 AkkStelleGBV
Signatory to the Multilateral Agreements of EA, ILAC and IAF for Mutual Recognition

Accreditation

The Deutsche Akkreditierungsstelle GmbH attests that the calibration laboratory

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

is competent under the terms of DIN EN ISO/IEC 17025:2018 and DIN EN ISO 15195:2019 to carry out calibrations in the following fields:

Medical reference measurement laboratories

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

The accreditation certificate shall only apply in connection with the notice of accreditation of 21.02.2022 with the accreditation number D-K-15027-01. It comprises the cover sheet, the reverse side of the cover sheet and the following annex with a total of 5 pages.

Registration number of the certificate: **D-K-15027-01-00**

by proxy

Berlin,	Dipl.-Wirtsch.-Ing. (BA) Tim Harnisch	Translation issued:	
21.02.2022	Head of technical unit	21.02.2022	Head of technical unit

The certificate together with its annex reflects the status at the time of the date of issue. The current status of the scope of accreditation can be found in the database of accredited bodies of Deutsche Akkreditierungsstelle GmbH.
https://www.dakks.de/en/content/accredited-bodies-dakks

This document is a translation. The definitive version is the original German accreditation certificate.

See notes overleaf.

Deutsche Akkreditierungsstelle GmbH

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Spittelmarkt 10
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Office Frankfurt am Main
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The accreditation was granted pursuant to the Act on the Accreditation Body (AkkStelleG) of 31 July 2009 (Federal Law Gazette I p. 2625) and the Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products (Official Journal of the European Union L 218 of 9 July 2008, p. 30). DAkkS is a signatory to the Multilateral Agreements for Mutual Recognition of the European co-operation for Accreditation (EA), International Accreditation Forum (IAF) and International Laboratory Accreditation Cooperation (ILAC). The signatories to these agreements recognise each other's accreditations.

The up-to-date state of membership can be retrieved from the following websites:
EA: www.european-accreditation.org
ILAC: www.ilac.org
IAF: www.iaf.nu

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Annex to the Accreditation Certificate D-K-15027-01-00 according to DIN EN ISO/IEC 17025:2018 and DIN EN ISO/IEC 15195:2019

Valid from: **21.02.2022**

Date of issue 21.02.2022

Holder of certificate:

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

Calibration in the fields:

Medical reference measurement laboratories
- **Amount of substance concentration**
- **Catalytic activity concentration**
- **Mass concentration**

The management system requirements of DIN EN ISO/IEC 17025 are written in the language relevant to the operations of calibration laboratories. Laboratories that conform to the requirements of this standard, operate generally in accordance with the principles of DIN EN ISO 9001.

The certificate together with the annex reflects the status as indicated by the date of issue.
The current status of any given scope of accreditation can be found in the directory of accredited bodies maintained by Deutsche Akkreditierungsstelle GmbH at https://www.dakks.de/en/accredited-bodies-search.html.

Abbreviations used: see last page

Permanent Laboratory

Calibration and Measurement Capabilities (CMC)

Measurement 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 %	
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 %	

[1)] The expanded uncertainties according to EA-4/02 M:2021 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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Permanent Laboratory

Calibration and Measurement Capabilities (CMC)

Measurement quantity / Calibration item	Range	Measurement conditions / procedure	Expanded uncertainty of measurement [1)]	Remarks
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 %	
Amount-of-substance concentration of glucose in urine	0,5 mmol/L to 60 mmol/L		1.0 %	

[1)] The expanded uncertainties according to EA-4/02 M:2021 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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Calibration and Measurement Capabilities (CMC)

Measurement quantity / Calibration item	Range	Measurement conditions / procedure	Expanded uncertainty of measurement [1)]	Remarks
Amount-of-substance concentration of uric acid in serum or material similar to serum	50 µmol/L to 1000 µmol/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 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. Bio-chem., 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 %	
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 %	

[1)] The expanded uncertainties according to EA-4/02 M:2021 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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Calibration and Measurement Capabilities (CMC)

Measurement quantity / Calibration item	Range	Measurement conditions / procedure	Expanded uncertainty of measurement [1)]	Remarks
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 58931:2021 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		2.5 %	
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:2021 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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