DAkkS
Deutsche
Akkreditierungsstelle

Accreditation

The Deutsche Akkreditierungsstelle attests with this **Accreditation Certificate** that the calibration laboratory

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

meets the requirements according to DIN EN ISO/IEC 17025:2018 for the conformity assessment activities listed in the annex to this certificate. This includes additional existing legal and normative requirements for the calibration laboratory, including those in relevant sectoral schemes, provided they are explicitly confirmed in the annex to this certificate.

The management system requirements of DIN EN ISO/IEC 17025 are written in the language relevant to the operations of calibration laboratories and they conform to the principles of DIN EN ISO 9001.

This accreditation was issued in accordance with Art. 5 Para. 1 Sentence 2 of Regulation (EC) 765/2008, after an accreditation procedure was carried out in compliance with the minimum requirements of DIN EN ISO/IEC 17011 and on the basis of a review and decision of the appointed accreditation committees.

This accreditation certificate only applies in connection with the notices of 21.02.2022 with accreditation number D-K-15027-01.
It consists of this cover sheet, the reverse side of the cover sheet and the following annex with a total of 5 pages.

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

Berlin, 10.04.2025
Dipl.-Wirtsch.-Ing. (BA) Tim Harnisch
Head of Technical Unit

Translation issued:
13.05.2025
Dipl.-Wirtsch.-Ing. (BA) Tim Harnisch
Head of Technical Unit

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 (www.dakks.de).

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

See notes overleaf

Deutsche Akkreditierungsstelle GmbH

Office Berlin
Spittelmarkt 10
10117 Berlin

Office Frankfurt am Main
Europa-Allee 52
60327 Frankfurt am Main

Office Braunschweig
Bundesallee 100
38116 Braunschweig

The Deutsche Akkreditierungsstelle GmbH (DAkkS) is the entrusted national accreditation body of the Federal Republic of Germany according to § 8 section 1 AkkStelleG in conjunction with § 1 section 1 AkkStelleGBV. DAkkS is designated as the national accreditation authority by Germany according to Art. 4 Para. 4 of Regulation (EC) 765/2008 and clause 4.7 of DIN EN ISO/IEC 17000.

Pursuant to Art. 11 section 2 of Regulation (EC) 765/2008, the accreditation certificate shall be recognised as equivalent by the national authorities within the scope of this Regulation as well as by the WTO member states that have committed themselves in bilateral or multilateral mutual agreements to recognise the certificates of accreditation bodies that are members of ILAC or IAF as equivalent.

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 Co-operation (ILAC).

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

DAkkS Deutsche Akkreditierungsstelle

Deutsche Akkreditierungsstelle

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

Valid from: **21.02.2022**

Date of issue: 01.07.2025

Holder of accreditation certificate:

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

with the location

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

The calibration laboratory meets the requirements of DIN EN ISO/IEC 17025:2018 to carry out the conformity assessment activities listed in this annex. The calibration laboratory meets additional legal and normative requirements, if applicable, including those in relevant sectoral schemes, provided that these are explicitly confirmed below.

The management system requirements of DIN EN ISO/IEC 17025 are written in the language relevant to the operations of calibration laboratories and they conform to the principles of DIN EN ISO 9001.

Calibration in the fields:

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

This certificate annex is only valid together with the written accreditation certificate and 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.

The calibration laboratory fullfills the additional aspects according to DIN EN ISO 15195:2019 with regard to competence in the field of laboratory medicine as a reference measurement laboratory.

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 %	
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 %	

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 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 %	
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)	1.0 %	

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 urea in urine	0.5 mmol/L to 500 mmol/L	Clin. Chem., 1999, 45, 1523-1529.	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 %	
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	Spectrophotometry 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 %	

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 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)