DAkkS
Deutsche
Akkreditierungsstelle

Accreditation

The Deutsche Akkreditierungsstelle attests with this **Accreditation Certificate** that

Stiftung für Pathobiochemie und Molekulare Diagnostik
Friesdorfer Straße 153, 53175 Bonn

operates a calibration laboratory that fulfills the requirements according to DIN EN ISO/IEC 17025:2018 for those conformity assessment activities specified in detail in the annex listed below. This includes additional existing legal and normative requirements for the calibration laboratory including those in relevant sectoral schemes, provided that these are explicitly confirmed in the annex listed below.

D-K-15117-02-01 **Valid from: 04.09.2025**

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 notice of 04.09.2025. It consists of this cover sheet, the reverse side of the cover sheet and the corresponding annex .

Registration number of the accreditation certificate: **D-K-15117-02-00**

Berlin, 04.09.2025 Dipl.-Wirtsch.-Ing. (BA) Tim Harnisch | Head of Technical Unit

Translation issued: 04.09.2025

See notes overleaf

Deutsche Akkreditierungsstelle GmbH

Office Berlin
Spittelmarkt 10
10117 Berlin

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

Deutsche Akkreditierungsstelle

Annex to the Accreditation Certificate D-K-15117-02-01 according to DIN EN ISO/IEC 17025:2018

Valid from: **04.09.2025**

Date of issue: 04.09.2025

This annex is part of the Accreditation Certificate D-K-15117-02-00.

Holder of the Accreditation Certificate:

Stiftung für Pathobiochemie und Molekulare Diagnostik
Friesdorfer Straße 153
53175 Bonn

with the location

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

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.

calibrations in the areas:

Medical reference measurement laboratories

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

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.

Measured quantity / Calibration item	Range			Measurement conditions / procedure	Best measurement capability	Remarks
Amount of substance concentration Glucose	0.5 mmol/L	to	25 mmol/L	ID-GC-MS, *in house* procedure, MHH-Hannover, date: 10/07/2018	1.0 %	System [a]: Serum, plasma, urine, blood, liquor
Bilirubin	5 µmol/L	to	525 µmol/L	Spectrophotometry Clin Chim Acta 2018;481:115-120	2.3 %	System[a]: Serum, Plasma
Hemoglobin	1.24 mmol/L	to	18.62 mmol/L	Spectrophotometry HiCN method Clin Chem Lab Med 2020; 58:1314-1321	1.1 %	System [a]: Blood [b]
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	Coulometry, *in house* procedure, MHH-Hannover, date: 10/07/2018	1.5 %	
Catalytic activity concentration Alanine aminotransferase (ALT)	0.072 µkat/L (4.3 U/L)	to	4.75 µkat/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 µkat/L (5.5 U/L)	to	11.3 µkat/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 %	

Measured quantity / Calibration item	Range			Measurement conditions / procedure	Best measurement capability	Remarks
α-Amylase (AMY)	0.058 µkat/L (3.5 U/L)	to	12.0 µkat/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 µkat/L (2.4 U/L)	to	4.17 µkat/L (250 U/L)	Kinetic photometric measurement of absorbance, IFCC reference measurement procedure (37°C), Clin Chem Lab Med 2002; 40:725–733	2.2 %	
Creatine kinase (CK)	0.155 µkat/L (9.3 U/L)	to	24.33 µkat/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 (1.9 U/L)	to	4.58 µkat/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 (8.7 U/L)	to	10.0 µkat/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 %	

[a] These systems are built up of native material or processed material similar to system material (lyophilised or liquid)

[b] The molar concentration applies to each subunit of the hemoglobin molecule (molecular mass of the Hb monomer: 16114.5 g/mol).

Abbreviations used:

CMC	Calibration and measurement capabilities
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