

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 provider of proficiency testing schemes

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

is competent under the terms of DIN EN ISO/IEC 17043:2010 to carry out proficiency testing in the following fields:

Immunology, Clinical Chemistry, Microbiology, Human Genetics, Transfusion Medicine and Virology

Utilising the proficiency testing materials blood and blood preparations, cerebrospinal fluid, serum, plasma, urine, lyophilized bacterial strains, lyophilized human cell cultures, cultures, sputum, faeces and aqueous solutions.

The accreditation certificate shall only apply in connection with the notice of accreditation of 15.03.2019 with the accreditation number D-EP-15027-02. 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-EP-15027-02-00**

Frankfurt am Main,
15.03.2019

Dipl.-Biol. Uwe Zimmermann
Head of Division

Translation issued:
29.03.2019


Signature
Head of Division

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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60327 Frankfurt am Main

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38116 Braunschweig

The publication of extracts of the accreditation certificate is subject to the prior written approval by Deutsche Akkreditierungsstelle GmbH (DAkKS). Exempted is the unchanged form of separate disseminations of the cover sheet by the conformity assessment body mentioned overleaf.

No impression shall be made that the accreditation also extends to fields beyond the scope of accreditation attested by DAkKS.

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

Deutsche Akkreditierungsstelle GmbH

Annex to the Accreditation Certificate D-PL-15027-02-00
according to DIN EN ISO/IEC 17043:2010

Valid from: 15.03.2019

Date of issue: 15.03.2019

Holder of certificate:

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

Proficiency testing in the following fields:

Immunology, Clinical Chemistry, Microbiology, Human Genetics, Transfusion Medicine and Virology

Utilising the proficiency testing materials blood and blood preparations, cerebrospinal fluid, serum, plasma, urine, lyophilized bacterial strains, lyophilized human cell cultures, cultures, sputum, faeces and aqueous solutions.

The organization that provides proficiency testing maintains a current list of all proficiency tests within the scope of accreditation.

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

Abbreviations used: see last page

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>

Immunology

Testing field	Matrices / Products	Measurands / test parameters*	Proficiency testing scheme (EQAS number)*
Allergy Diagnostics	Serum	Spec. IgE-AK, Total IgE	Allergy Diagnostics (720)
Immunology	Serum Plasma	CRP, Ferritin	hsCRP (240), Plasmaproteins 01 (241)

* exemplary list

Clinical Chemistry

Testing field	Matrices / Products	Measurands / test parameters*	Proficiency testing scheme (EQAS number)*
Amino Acid Analysis	Plasma Urine	Tyrosine, Alanine	Amino Acid Analysis (710)
Autoimmune Diseases	Serum Plasma	ANA, pANCA	Autoimmune Diseases 01 (251) Autoimmune Diseases 04 (257)
Blood Gas Analysis	Aqueous solutions, blood and blood preparations	pH, pCO ₂	Blood Gas Analysis (161)
Glycated Proteins	Blood and blood preparations	HbA1c	Glycated Proteins (145)
Haematology	Blood and blood preparations	Haemoglobin, Leukocytes	Blood Cell Count (211) Differential Blood Count (Machine-Based Analysis) (612/912)
Haemostasiology	Plasma	INR, aPTT, Fibrinogen	Haemostasiology 01 - TPT, INR, aPTT (221), Haemostasiology 02 - FIB, TZ, FSP (222)
Hormones	Serum Plasma	T4, Testosterone	Thyroid Hormones (294), Steroid Hormones, (302)
Clinical Chemistry	Serum Plasma Urine	Potassium, Glucose, Bilirubin	Clinical Chemistry – (Conventional Analysis) (100), Neonatal Bilirubin (110)
Cerebrospinal Fluid Diagnostics	Cerebrospinal fluid Serum	Total protein, IgA	CSF Analysis 01 - Protein Analysis (460), CSF Analysis 02 - Oligoclonal IgG (462)
Pharmaceuticals	Serum Plasma Blood and blood preparations	Amiodarone, Digoxin	Pharmaceuticals Antiarrhythmics - Amiodaron (190), TDM 01 (195)
Psychotropic Drugs	Serum Plasma Blood and blood preparations	Perazine, Venlafaxine	Psychotherapeutic Drugs 01 (860)
Pregnancy Diagnostics	Serum Plasma	Free β-hCG, PAPP A	Fertility - 1st Trimester Screening (305)
Trace Elements	Serum Plasma Blood Urine	Arsenic, Lead	Trace Elements 01 (205)
Dry Chemistry	Serum Plasma	Potassium, Glucose	Dry Chemistry 02 – POCT: Abaxis Piccolo System (810)

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Annex to the accreditation certificate D-PL-15027-02-00

Testing field	Matrices / Products	Measurands / test parameters*	Proficiency testing scheme (EQAS number)*
Urine Analysis	Urine	Leukocytes, Serotonin	Urine Chemistry 01 (qualitative) (171), Urine Chemistry 03 (Biogenic Amines) (175)

* exemplary list

Microbiology

Testing field	Matrices / Products	Measurands / test parameters*	Proficiency testing scheme (EQAS number)*
Bacterial Genome Detection	Lyophilized human cell cultures with inactivated pathogens / nucleic acids	Bordetella pertussis Borrelia burgdorferi	Bordetella pertussis (532) Borrelia burgdorferi (535)
Bacteriology	Lyophilized bacterial strains	Gram staining, Bacteria identification, Sensitivity testing	Bacteriology - 5 Strains (412) Bacteriology - 3 Strains (411)
Bacteriological Infection Serology	Serum	Bordetella pertussis ab Borrelia burgdorferi ab	Bordetella pertussis Antibodies (317) Borrelia burgdorferi Antibodies (332)
Mycology	Cultures	Differentiation of fungi	Mycology 01 Yeasts, Hyphomycetes (490)
Mycoserology	Serum Plasma	Candida ab Candida antigen Cryptococcus neoformans antigen	Mycoserology 01 (480) Mycoserology 02 (481)
Parasite Diagnostics	Blood and blood preparations faeces Serum Plasma	Microscopic parasite detection in faeces and blood Detection of ab against parasites	Parasite Microscopy (faeces) (451), Parasite Microscopy (Blood) (456) Parasite Serology: Amebiasis and Echinococcosis (455)
Fungal Genome Detection	Lyophilized human cell culture with inactivated pathogens / nucleic acids	Pneumocystis jirovecii	Fungal Genome Detection: Pneumocystis jirovecii (560)
Tuberculosis	Microscopic specimens Sputum Cultures	Detection of acid-fast bacilli Detection of mycobacteria by culture and (optional) identification of tubercle-bacilli Identification of mycobacteria	Mycobacteriology 01: Microscopy (421) Mycobacteriology 02: Culture (422) Mycobacteriology 03: Identification (423)

* exemplary list

-Translation-

Transfusion Medicine

Testing field	Matrices / Products	Measurands / test parameters*	Proficiency testing scheme (EQAS number)*
Immunogenetics / HLA	Serum Plasma Blood and blood preparations	HLA-B27, Determination of HLA Class I Characteristics	Immunogenetics 01 – HLA-B27 Determination (440), Immunogenetics 02 – Serology HLA Typing Class I and II (441)
Immunohaematology	Blood and blood preparations	AB0, Rh	Immunohaematology 01 (231)

* exemplary list

Human Genetics

Testing field	Matrices / Products	Measurands / test parameters*	Proficiency testing scheme (EQAS number)*
Molecular Genetics	Blood and blood preparations aqueous DNA solutions	MTHFR C677T	Molecular Genetics 01 MTHFR C677T (optional A1298C) (732), (730-735)

* exemplary list

Virology

Testing field	Matrices / Products	Measurands / test parameters*	Proficiency testing scheme (EQAS number)*
Virus Genome Detection	Serum Plasma Cell culture lyophilisates	HIV-1 (RNA), Human papilloma viruses	HIV-1 (RNA) (360), Human Papilloma Viruses (373)
Virus Immunology	Serum Plasma	HIV-1/HIV-2 (ab) HIV-1 p24-Antigen	HIV-1 / HIV-2 (335), HIV-1 p24 Antigen (337)

* exemplary list

-Translation-

Annex to the accreditation certificate D-PL-15027-02-00

Statistical evaluation:

Guideline of the German Medical Association for Quality Assurance of Laboratory Medical Examinations, last amended 20.06.2014, Deutsches Ärzteblatt Jg. 111, Issue 38 of 19.09.2014, page A1583ff.

INSTAND QM system:

Auswertung von Ringversuchen – Zielwerte und Statistik (DV-VA-004)

abbreviations used:

DIN German Institute for Standardization e.V.
EN European Standard
IEC International Electrotechnical Commission
ISO International Organization for Standardization
DV-VA Procedural instruction (document) of INSTAND e. V.

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