

Accreditation



The Deutsche Akkreditierungsstelle attests with this **Accreditation Certificate** that the proficiency testing provider

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

meets the requirements according to DIN EN ISO 15189:2024 for the conformity assessment activities listed in the annex to this certificate. This includes additional existing legal and normative requirements for the medical 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 17043 are written in the language relevant to the operations of proficiency testing providers 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 13.11.2024 with accreditation number D-EP-15117-01.
It consists of this cover sheet, the reverse side of the cover sheet and the following annex with a total of 11 pages.

Registration number of the accreditation certificate: **D-EP-15117-01-00**

Berlin, 13.11.2024

Dipl.-Ing. Anna Lewandowski
Head of Technical Unit

Translation issued:
TT.MM.2025

Dipl.-Ing. Anna Lewandowski
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

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10117 Berlin

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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-EP-15117-01-00 according to DIN EN ISO/IEC 17043:2023

Valid from: 13.11.2024

Date of issue: 13.11.2024

Holder of accreditation certificate:

**Stiftung für Pathobiochemie und Molekulare Diagnostik
Referenzinstitut für Bioanalytik
Friesdorfer Straße 153, 53175 Bonn, Germany**

with the location

**Stiftung für Pathobiochemie und Molekulare Diagnostik
Referenzinstitut für Bioanalytik
Friesdorfer Straße 153, 53175 Bonn, Germany**

The proficiency testing provider meets the requirements of DIN EN ISO/IEC 17043:2010 to carry out the conformity assessment activities listed in this annex. The proficiency testing provider 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 17043 are written in the language relevant to the operations of proficiency testing providers and they conform to the principles of DIN EN ISO 9001.

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>.

Abbreviations used: see last page

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Annex to the Accreditation Certificate D-EP-15117-01-00
Proficiency testing in the field of Medical Laboratory Diagnostics
Investigation Fields:

Clinical Chemistry

Immunology

Transfusion medicine

Microbiology

Virology

Human genetics (Molecular human genetics)

The proficiency testing provider maintains a current list of all proficiency tests within the scope of accreditation.

1 Proficiency testing in the field of Medical laboratory Diagnostics
1.1 Investigation Field: Clinical Chemistry

Testing field	Matrix / Products	Test parameters/ Analytes*	Proficiency Testing schemes*
Pharmaceutical determinations	Serum	Carbamazepin, Digoxin, Lithium	Proficiency Test Pharmaceuticals (AK)
Ammonia determination	Serum	Ammonia	Proficiency Test Ammonia (AM)
Neonatal bilirubin determination	Serum	Total-Bilirubin, Bilirubin unconjugated, Bilirubin conjugated	Proficiency Test Neonatal bilirubin determination (BI)
Blood gas analysis	Gas-equilibrated solutions	pH, pCO ₂ , pO ₂ , Sodium, Potassium	Proficiency Test Blood gas analysis (BG)
Ciclosporin	Hemolyzed blood	Ciclosporin	Proficiency Test Ciclosporin (CS)
Cardiac markers	Serum, whole blood	CK-MB, Troponin	Proficiency Test Cardiac markers (CM and CMX)
Drug screening	Urine	Amphetamines, Barbiturates, Benzodiazepines, Cannabinoides	Proficiency Test Drug screening (DS)
CD transferrin (CDT)	Serum	CDT relative, total	Proficiency Test Transferrin (DT)
Ethanol determination	Serum	Ethanol	Proficiency Test Ethanol determination (ET)

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Testing field	Matrix / Products	Test parameters/ Analytes*	Proficiency Testing schemes*
Glycated hemoglobin Determination (HbA1c)	Whole blood	HbA1c	Proficiency Test Glycated hemoglobin Determination HbA1c (GH)
Glucose "wet chemistry" and "dry chemistry"	Serum	Glucose	Proficiency Test Glucose "wet chemistry" (GL) and "dry chemistry"(TR)
Hormone determinations	Serum	Cortisol, Estradiol- 17beta, Progesteron, FSH, LH, Prolactin	Proficiency Test Hormone determinations (HM) / (HP)
Urinary stone	Urinary stone components	calculus components (pure, mixed)	Proficiency Test Urinary stone (HS)
Serum proteins	Serum	albumin, transferrin, IgA, IgG, IgM	Proficiency Test Serum proteins (IG)
Clinical chemical analytes	Cerebrospinal fluid (CSF)	glucose, lactat, total protein, L-albumin	Proficiency Test Clinical chemical analytes in cerebrospinal fluid (KL)
Clinical chemical analytes	Serum	bilirubin total, bilirubin direct, cholesterol, glucose	Proficiency Test Clinical chemical analytes in serum "wet chemistry" (KS)
Clinical chemical analytes	Urine	glucose, uric acid, urea, creatinine	Proficiency Test Clinical chemical analytes in urine (KU)
Urine test strip and pregnancy test	Urine	Test strip: pregnancy, pH, protein, glucose	Proficiency Test Urine test strip and pregnancy test (KUST)
Lipoproteins	Serum	cholesterol, triglycerides, apolipoprotein A1, Lipoprotein (a)	Proficiency Test Lipoproteins (LP)
Oligoclonal bands	Cerebrospinal fluid, serum (CSF)	band pattern type, OB- test, bands CSF	Proficiency Test ligoclonal bands in cerebrospinal fluid (OB)
Hemoglobin derivates	Hemolysat	hemoglobin, methemoglobin	Proficiency Test Hemoglobin- derivates (OH)
Photometer control	Aqueous coloured solutions	260,0 nm, 280,0 nm, 334,1 nm, 340,0 nm,	Proficiency Test Photometer control (PH)

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Testing field	Matrix / Products	Test parameters/ Analytes*	Proficiency Testing schemes*
		365,5 nm, 404,7 nm, 546,1 nm, 560,0 nm	
Pregnancy diagnostic	Serum	AFP, hCG, PAPP-A, free beta-hCG	Proficiency Test Pregnancy diagnostic (SD)
Trace elements	Urine	aluminium, arsenic total, lead, cadmium, chromium	Proficiency Test Trace elements (SP)
Systematic toxicologic analysis	Urine	Amitriptylin, Bisacodyl, Bromazepam, Chlorprothixen	Proficiency Test systematic toxicologic analysis (SX)
Tumor markers	Serum	CA 125, CA 15-3, CA 19- 9, CA 72-4, CEA, hCG, PSA, Chromogranin A	Proficiency Test Tumor markers (TM and TMX)
Carrier-bound reagents dry chemistry	Serum	bilirubin total, cholesterol, glucose, uric acid	Proficiency Test Carrier- bound reagents (Clinical chemical analytes in serum) dry chemistry (TR)
Newborn screening	Filter papers with dried drop of blood	TSH, 17-OH- progesterone	Proficiency Test Newborn screening (NBS)
Toxicology	Urine, serum	Technical evaluation, medical interpretation	Proficiency Test Toxicology (TX)
Urine sediment	Web-based, virtual microscopy of urine sediments	erythrocytes, leukocytes	Proficiency Test Urine sediment (US)
Vitamins and analgesics	Serum	vitamin A, B1, B6, B12, 25-OH-cholecalciferol, folic acid, salicylic acid, paracetamol	Proficiency Test Vitamins and analgesics (VT)
Cell count in cerebrospinal fluid	Cerebrospinal fluid (CSF)	leukocytes, erythrocyte	Proficiency Test Cell count in cerebrospinal fluid (ZL)
Cytokines	Serum	IL-6, IL-8, IL-10, TNF alpha, PCT	Proficiency Test Cytokines (ZY)
Cerebrospinal fluid cytospin preparation	Exclusively web- based proficiency Test	assessment	Proficiency Test Cerebrospinal fluid cytospin preparation (ZZ)
Hematology			

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Testing field	Matrix / Products	Test parameters/ Analytes*	Proficiency Testing schemes*
Automatic differential count	Whole blood	neutrophile granulocytes, lymphocytes, monocytes	Proficiency Test Automatic differential count (AD)
Differential blood count	Smears, dyed	Leucocyte population, morphology, tentative diagnosis	Proficiency Test Differential blood count (DF)
Small blood count	Blood preparation	hemoglobin, erythrocytes, leukocytes	Proficiency Test Small Blood count (HA)
Reticulocytes	Blood preparation	Retikulocytes relative and total	Proficiency Test Retikulocytes (RE)
Immuno status (Flow cytometry)	Blood preparation	Leukocytes count, lymphocytes, Lymphocytes count, CD3+	Proficiency Test/Flow cytometry (IS)
Hemostaseology			
D-Dimer	Plasma	D-Dimer	Proficiency Test D-Dimer (DD)
Coagulation analysis	Plasma	Prothrombin time (Quick), TPZ INR, aPTT, thrombin time (TZ/PTZ)	Proficiency Test Coagulation analysis (GR)

*exemplary list

1.2 Investigation Field: Immunology

Testing field	Matrix / Products	Test parameters/ Analytes*	Proficiency Testing schemes*
Specific (Antinuclear) antibodies	Serum	Specific autoantibodies ANA (antinuclear ab), ENA-screening-test, Sm-RNP	Proficiency Test Specific (Antinuclear) antibodies (AI)
Allergology	Serum	total IgE, specific IgE antibodies	Proficiency Test Allergology (AL)
Thyroid antibodies	Serum	Anti-TG (TAK), Anti-TPO (MAK), Anti-TSH-Rez (TRAK)	Proficiency Test Thyroid antibodies (SA)

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Testing field	Matrix / Products	Test parameters/ Analytes*	Proficiency Testing schemes*
Rheumatoid factors	Serum	Rheumatoid factors, Anti-CCP-Ab, IgM-RF, IgG-RF	Proficiency Test Rheumatoid factors (RF)
Immunophenotyping (flow cytometrie)	Blood preparation	leukocyte count, lymphocyte count, CD3+ a. o.	Proficiency Test Immunophenotyping (flow cytometrie) (IS)
Cytokines	Serum	IL-6, IL-8, IL-10, TNF alpha, PCT	Proficiency Test Cytokines (ZY)

*exemplary list

1.3 Investigation Field: Transfusion medicine

Testing field	Matrix / Products	Test parameters/ Analytes*	Proficiency Testing schemes*
Immunhematology for automated systems	Whole blood	ABO-system (features), A-subgroups , rhesus- factor	Proficiency Test Immunhematology (IA)
Immunhematology Major (extended offer)	Erythrocytes- suspension, serum	ABO-system (features), A-subgroups , rhesus- factor	Proficiency Test Immunhematology (IH)
Immunhematology Minor (basic program)	Erythrocytes- suspension, serum	ABO-system (features), A-subgroups , rhesus- factor	Proficiency Test Immunhematology (IM)

*exemplary list

1.4 Investigation Field: Virology

Testing field	Matrix / Products	Test parameters/ Analytes*	Proficiency Testing schemes*
Virus serology	Serum, plasma	Anti-CMV IgG + gesamt, Anti-CMV IgM	Proficiency Test CMV serology (CMVimm)
Virus serology	Serum, plasma	Anti-HAV IgG, Anti-HAV IgM, Anti-HAV total	Proficiency Test HAV serology (HAVimm)
Virus serology	Serum, plasma	HBsAg, Anti-HBs, Anti- HBc	Proficiency Test HBV serology minor (HBVimm1)

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Testing field	Matrix / Products	Test parameters/ Analytes*	Proficiency Testing schemes*
Virus serology	Serum, plasma	HBsAg, Anti-HBs, Anti-HBc, HBeAg, Anti-HBe, Anti-HBc-IgM	Proficiency Test HBV serology major (HBVimm2)
Virus serology	Serum, plasma	Anti-HCV IgG + IgM	Proficiency Test HCV serology (HCVimm)
Virus serology	Serum, plasma	Anti-HCV 1/2 Ak / Ag(p24)	Proficiency Test HCV serology (HIVimm)
Virus serology	Plasma	Anti-HTLV 1/2 IgG	Proficiency Test HTLV serology (HTLVimm)
Virus serology	serum, plasma	Anti-Parvo B19 IgG + gesamt, Anti-Parvo B19 IgM	Proficiency Test Parvovirus B19 serology (pvB19imm)
Virus genome verification	Plasma	HEV-RNA	Proficiency Test Hepatitis E virus (HEVpcr)
Virus genome verification	NaCl-solution	Norovirus RNA	Proficiency Test Norovirus-PCR (NOROpqr)
Virus serology	Serum, plasma	Anti-rubella virus IgG, IgM	Proficiency Test Anti-rubella virus (RoetLimm)
Virus genome verification	Cell culture supernatant	SARS-CoV-2 RNA, SARS-CoV-2 RNA-variants	Proficiency Test genome verification SARS-CoV-2 and Variants (CoVpcr)
Virus genome verification	Cell culture supernatant	SARS-CoV-2 Antigen	Proficiency Verification SARS-CoV-2 Antigen (CoVag)
Virus genome verification	Plasma	Measles virus DNA, Mumps virus RNA, Rubella virus DNA	Proficiency Test Measles, Mumps, Rubella genome verification (MMRpqr)
Virus serology	Serum	Anti-CoV-2 IgG total, Anti-S-CoV-2 IgG, Anti-N-CoV-2 IgG	Proficiency Verification SARS-CoV-2-immunology

*exemplary list

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1.5 Investigation Field: Microbiology

Testing field	Matrix / Products	Test parameters/ Analytes*	Proficiency Testing schemes*
Bacteriology	Lyophilized control samples	Cultivation, Identification and resistance testing of bacteria	Proficiency Test Bacteriology Major (BA) 5 strains; Proficiency Test Bacteriology Minor (BM) 3 strains
Bacteriology	Urine	chlamydia trachomatis antigen	Proficiency Test chlamydia trachomatis antigen (ChlamTra)
Bacteriology	Unstained smears	assessment of gram behavior, morphology	Proficiency Test Gram-Staining (GP)
Mycology	Serum	cryptococcus neoformans, candida albicans antigen	Proficiency Test cryptococcus neoformans, candida albicans antigen (CrypCand)
Mycology	Lyophilized fungal strains	Cultivation, Identification of fungi	Proficiency Test Cultivation, Identification of fungi (MykCult)
Mycology	Virtual microscopy of preparations	Identification of fungi	Proficiency Test Identification of fungi (MykIdent) (virtual microscopy)
Parasitology	Virtual microscopy preparations of blood and faeces	Identification of parasites	Proficiency Test Identification of parasites (ParasitB and ParasitS)
Infection serology	Plasma, serum	Anti-Toxoplasma gondii IgG-, IgM-Antibody, Anti-Toxoplasma gondii total	Proficiency Test Anti-Toxoplasma gondii (ToxoGimm)
Infection serology	Plasma, serum	Anti-Treponema pallidum total, Anti-Treponema pallidum IgG-, IgM	Proficiency Test Anti-Treponema pallidum (TrepPimm)
Infection serology	Plasma, serum	Anti-Candida albicans IgG, Anti-Echinococcus IgG, Anti-Entamoeba histolytica-IgG, Anti-	Proficiency Test Various Proficiency Test immunological analytes (VariAimm)

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Testing field	Matrix / Products	Test parameters/ Analytes*	Proficiency Testing schemes*
		Plasmodien total, Anti-Schistosoma IgG, Anti-Streptococcus DNase	
Infection serology	Plasma, serum	Anti-Borrelia burgdorferi IgG, IgM, total	Proficiency Test Anti-Borrelia burgdorferi (BorrBimm)
Genom detectionv (Bacteriology, Mycobacteria, Parasites)	Lyophilized DNA	Genom detection of bacteria, mycobacteria, parasites	Genom detection of bacteria (BAK NAT 1 and 2 and 3, CdToxin) Parasites (ToxoGen)

*exemplary list

1.6 Investigation Field: Human genetics (Molecular human genetics)

Testing field	Matrix / Products	Test parameters/ Analytes*	Proficiency Testing schemes*
DNA-isolation	K-EDTA-whole blood	FV-Leiden (ARG506GLN), FV-H1299R (HIS1299ARG), FV-Cambridge (ARG306THR)	Proficiency Test DNA-isolation (DI)
Molecular genetics	DNA-preparation	Factor V (Leiden), Factor II 20210, MTHFR, PAI-1	Proficiency Test Molecular genetics (MG)

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Testing field	Matrix / Products	Test parameters/ Analytes*	Proficiency Testing schemes*
Molecular genetics	EDTA-Plasma	"KRAS proto-oncogene, GTPase U - KRAS p.G12 (KRAS, NM_004985.S:c.34G>T>C >A, rs121913530) - KRAS p.G12 (KRAS, NM_004985.5:c.35G>T>C >A, rs121913529) - KRAS p.G13 (KRAS, NM_004985.5:c.37G>T>C >A, rs121913535) - KRAS p.G13 (KRAS, NM_004985.5:c.38G>T>(>A, rs112445441) 8-Raf proto-oncogene, serine/threonine kinase I - BRAF p.V600E (BRAF, NM_004333.6:c.I799T>A rs113488022) Epidermal growth factor receptor U - EGFR p.T790M (EGFR, NM_005228.5:c.2369C>T rs121434569) NRAS proto-oncogene, GTPase U - NRAS p.Q61 (NRAS, NM_002524.S:c.181C>T> G>A, rs121913254) - NRAS p.Q61 (NRAS, NM_002524.5:c.182A>T> G>C, rs11554290) - NRAS p.Q61 (NRAS, NM_002524.5:c.183A>T> C, rs121913255)"	Proficiency Test ctDNA – circulating tumor DNA (ctDNA)

¹exemplary list

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The requirements for reference institutions in Part E of the Guideline of the German Medical Association (Rili-BÄK) for the quality assurance of laboratory medical examinations in accordance with the resolution of the Executive Board of the German Medical Association at its meeting on October 18, 2019, last amended by resolutions of the Executive Board of the German Medical Association on April 14, 2023. 04.2023, are fulfilled with regard to the special parts B1 "Quantitative laboratory medical examinations", B2 for "Qualitative laboratory medical examinations", B3 "Detection and characterization of infectious agents" and B5 for "Molecular genetic and cytogenetic laboratory medical examinations".

Abbreviations used:

DIN	Deutsches Institut für Normung e.V. – German institute for standardization
EN	Europäische Norm – European Standard
ISO	International Organization for Standardisation
IEC	International Electrotechnical Commission