

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

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

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

Medical Laboratory Diagnostics

Investigation Fields:

Clinical Chemistry, Immunology, Microbiology, Virology, Humangenetics, Transfusion medicine

The accreditation certificate shall only apply in connection with the notice of accreditation of 24.04.2020 with the accreditation number D-EP-15117-01. It comprises the cover sheet, the reverse side of the cover sheet and the following annex with a total of 9 pages.

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

Frankfurt am Main,
24.04.2020

Dipl.-Biol. Uwe Zimmermann
Head of Division

Translation issued:
24.04.2020


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

Office Berlin
Spittelmarkt 10
10117 Berlin

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

Office Braunschweig
Bundesallee 100
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-EP-15117-01-00 according to DIN EN ISO/IEC 17043:2010

Valid from: 24.04.2020

Date of issue: 24.04.2020

Holder of certificate:

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

Proficiency testing in the fields:

Medical Laboratory Diagnostics

Investigation Fields:

Clinical Chemistry, Immunology, Microbiology, Virology, Human genetics, Transfusion medicine

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

Investigation Field: Clinical Chemistry

Testing field	Matrix / Products	Test parameters/ Analytes	Proficiency Testing schemes ¹
Pharmaceutical determinations	Serum	Carbamazepin, Digoxin, Lithium a. o.	Proficiency Test Pharmaceuticals (AK)
Ammonia determination	Serum	Ammonia	Proficiency Test Ammonia (AM)
Neonatal bilirubin determination	Serum	Total-Bilirubin, Bilirubin unconjugated, Bilirubin conjugated a. o.	Proficiency Test Neonatal bilirubin determination (BI)
Blood gas analysis	Gas-equilibrated solutions	pH, pCO ₂ , pO ₂ , Sodium, Potassium a. o.	Proficiency Test Blood gas analysis (BG)
Immunosuppressants	Hemolyzed blood	Ciclosporin, a. o.	Proficiency Test Ciclosporin (CS)
Cardiac markers	Serum, whole blood	CK-MB, Troponin, a. o.	Proficiency Test Cardiac markers (CM and CMX)
Drug screening	Urine	Amphetamines, Barbiturates, Benzodiazepines, Cannabinoide a. o.	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)
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 a. o.	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 u. a.	Proficiency Test Serum proteins (IG)

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Testing field	Matrix / Products	Test parameters/ Analytes	Proficiency Testing schemes ¹
Clinical chemical analytes	Cerebrospinal fluid (CSF)	glucose, lactat, total protein, L-albumin a. o.	Proficiency Test Clinical chemical analytes in cerebrospinal fluid (KL)
Clinical chemical analytes	Serum	bilirubin total, bilirubin direct, cholesterol, glucose a. o.	Proficiency Test Clinical chemical analytes in serum "wet chemistry" (KS)
Clinical chemical analytes	Urine	glucose, uric acid, urea, creatinine a. o.	Proficiency Test Clinical chemical analytes in urine (KU)
Urine test strip and pregnancy test	Urine	Test strip: pregnancy, pH, protein, glucose, a. o.	Proficiency Test Urine test strip and pregnancy test (KUST)
Lipoproteins	Serum	cholesterol, triglycerides, apolipoprotein A1, Lipoprotein (a) a. o.	Proficiency Test Lipoproteins (LP)
Oligoclonal bands	Cerebrospinal fluid, serum (CSF)	band pattern type, OB-test, bands CSF a.o.	Proficiency Test Oligoclonal bands in cerebrospinal fluid (OB)
Hemoglobin derivates	Hemolysat	hemoglobin, methemoglobin a. o.	Proficiency Test Hemoglobin-derivates (OH)
Photometer control	Aqueous coloured solutions	260,0 nm, 280,0 nm, 334,1 nm, 340,0 nm, 365,5 nm, 404,7 nm, 546,1 nm, 560,0 nm	Proficiency Test Photometer control (PH)
Pregnancy diagnostic	Serum	AFP, hCG, PAPP-A, free beta-hCG a. o.	Proficiency Test Pregnancy diagnostic (SD)
Trace elements	Urine	aluminium, arsenic total, lead, cadmium, chromium a. o.	Proficiency Test Trace elements (SP)
Systematic toxicologic analysis	Urine	Amitriptylin, Bisacodyl, Bromazepam, Chlorprothixen u. o.	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 a.o.	Proficiency Test Tumor markers (TM and TMX)
Carrier-bound reagents dry chemistry	Serum	bilirubin total, cholesterol, glucose, uric acid, a. o.	Proficiency Test Carrier-bound reagents (Clinical chemical analytes in serum)

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Testing field	Matrix / Products	Test parameters/ Analytes	Proficiency Testing schemes ¹
			dry chemistry (TR)
Newborn screening	Filter papers with dried drop of blood	TSH, 17-OH-progesterone, a. o.	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 a. o.	Proficiency Test Vitamins and analgesics (VT)
Cell count in cerebrospinal fluid	Cerebrospinal fluid (CSF)	leukocytes, erythrocyte	Proficiency Test Cell count in cerebrospinal fluid (ZL)
Cerebrospinal fluid cytospin preparation	Exclusively web-based proficiency Test	assessment	Proficiency Test Cerebrospinal fluid cytospin preparation (ZZ)
Sweat	Sweat preparation	Chloride, conductivity	Proficiency Test Sweat analytic (SW)
Saliva	Saliva preparation	Cortisol, 17-OH Progesteron	Proficiency Test Saliva diagnostic (SV)
Feces-Diagnostic	Feces	Hemoglobin, Hemoglobin-, Haptoglobin- complex, pancr. Elastase-1, Calprotectin	Proficiency Test Feces-Diagnostic (FD)
Hematology			
Automatic differential count	Whole blood	neutrophile granulocytes, lymphocytes, monocytes a. o.	Proficiency Test Automatic differential count (AD)
Differential blood count	Smears, dyed	Leucocytepopulation, morphology, tentative diagnosis	Proficiency Test Differential blood count (DF)
Small blood count	Blood preparation	hemoglobin, erythrocytes, leukocytes a. o.	Proficiency Test Small Blood count (HA)
Reticulocytes	Blood preparation	Retikulocytes relative and total	Proficiency Test Retikulocytes (RE)
Hemostaseology			
D-dimer	Plasma	D-dimer	Proficiency Test D-dimer (DD)

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Testing field	Matrix / Products	Test parameters/ Analytes	Proficiency Testing schemes ¹
Coagulation analysis	Plasma	Prothrombin time (Quick), TPZ INR, aPTT, thrombin time (TZ/PTZ) a. o.	Proficiency Test Coagulation analysis (GR)

¹exemplary list

Investigation Field: Immunology

Testing field	Matrix / Products	Test parameters/ Analytes	Proficiency Testing schemes ¹
Specific (Antinuclear) antibodies	Serum	Specific autoantibodies ANA (antinuclear ab), ENA-screening-test, a. o.	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)
Rheumatoid factors	Serum	Rheumatoid factors, Anti-CCP-Ab, IgM-RF, IgG-RF a. o.	Proficiency Test Rheumatoid factors (RF)
Cytokines	Serum	IL-6, IL-8, IL-10, TNF alpha, PCT a. o.	Proficiency Test Cytokines (ZY)
Immunophenotyping (flow cytometrie)	Blood preparation	leukocyte count, lymphocyte count, CD3+ a. o.	Proficiency Test Immunophenotyping (flow cytometrie) (IS)

¹exemplary list

Investigation Field: Transfusion medicine

Testing field	Matrix / Products	Test parameters/ Analytes	Proficiency Testing schemes ¹
Immunhematology for automated systems	Whole blood	ABO-system (features), A-subgroups, rhesus-factor a. o.	Proficiency Test Immunhematology (IA)
Immunhematology Major (extended offer)	Erythrocytes-suspension, serum	ABO-system (features), A-subgroups, rhesus-factor a. o.	Proficiency Test Immunhematology (IH)
Immunhematology Minor (basic program)	Erythrocytes-suspension, serum	ABO-system (features), A-subgroups, rhesus-factor a. o.	Proficiency Test Immunhematology (IM)

*exemplary list

Investigation Field: Virology

Testing field	Matrix / Products	Test parameters/ Analytes	Proficiency Testing schemes ¹
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)
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 serology	Plasma	Anti-HSV 1, 2 IgG + IgM, Anti-VZV IgG + IgM	Proficiency Test Herpes-Virus Serology
Virus serology	Plasma	EBNA IgG, EBV-VCA IgG + IgM, EBV-EA IgG	Proficiency Test Epstein-Barr-Virus- Serology (EBVimm)
Virus serology	Plasma	Anti-Rubeola, IgG, Anti- Rubeola, IgM Anti- Mumps, IgG Anti- Mumps IgM	Proficiency Test Rubeola and Mumps-Virus Serology (MaMuimm)
Virology	Samples in NaCl Matrix	Influenza A/B Antigen, RSV Antigen	Proficiency Test Influenza und RSV Antigen (Infl-RSV)
Virus genome verification	Plasma	HEV-RNA	Proficiency Test Hepatitis E virus (HEVpcr)
Virus genome verification	NaCl-solution (matrix)	Norovirus RNA	Proficiency Test Norovirus- PCR (NOROpCr)
Virus genome verification	Plasma	HAV, HBV, HCV, HIV- 1/2, CMV, Parvovirus B19, WNV	Proficiency Test PolyVir1

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Testing field	Matrix / Products	Test parameters/ Analytes	Proficiency Testing schemes ¹
Virus genome verification	Virus-DNA in NaCl-Matrix	Adenovirus, EBV, Enterovirus, HPV, HSV1/2, Influenza A/B, RSV, VZV	Proficiency Test PolyVir2
Virus serology	Serum, plasma	Anti-rubella virus IgG, IgM a.o.	Proficiency Test Anti-rubella virus (RoetLimm)

¹exemplary list

Investigation Field: Microbiology

Testing field	Matrix / Products	Test parameters/ Analytes	Proficiency Testing schemes ¹
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)
Bacteriology	Smear tube	MRGN-Screening	Proficiency Test MRGNscre
Bacteriology	Smear tube	MRSA-Screening	Proficiency Test MRSA Scre
Bacteriology	Smear tube	B-Streptokokken-Screening	Proficiency Test B-Stscre
Bacteriology	Thrombocytes concentrate	Detection of bacteria in TC	Proficiency Test Bak-TK
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

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Testing field	Matrix / Products	Test parameters/ Analytes	Proficiency Testing schemes ¹
			(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-Plasmodien total, Anti-Schistosoma IgG, Anti-Streptococcus DNase	Proficiency Test Various Proficiency Test immunological analytes (VariAimm)
Infection serology	Plasma, serum	Anti-Borrelia burgdorferi IgG, IgM, total	Proficiency Test Anti-Borrelia burgdorferi (BorrBimm)
Genom detection	Lyophilized DNA	Genom detection of bacteria, mycobacteria, parasites	Proficiency Test Genom detection of bacteria BakNAT1 and 2

¹exemplary list

Investigation Field: Human genetics (Molecular human genetics)

Testing field	Matrix / Products	Test parameters/ Analytes	Proficiency Testing schemes ¹
DNA-isolation	K-EDTA-whole blood	FV-Leiden (ARG506GLN), FV-H1299R (HIS1299ARG), FV-Cambridge (ARG306THR) a. o.	Proficiency Test DNA-isolation (DI)
Molecular biology	DNA-preparation	Factor V (Leiden), Factor II 20210, MTHFR, PAI-1 u. a.	Proficiency Test Molecular biology (FV)
DNA-sequencing	DNA-preparation	DNA-sequencing Sanger technology	Proficiency Test DNA-sequencing (SQ)

¹exemplary list

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statistical evaluation:

Richtlinie der Bundesärztekammer zur Qualitätssicherung labormedizinischer Untersuchungen vom 11.04.2014 und 20.06.2014, Deutsches Ärzteblatt Jg. 111, Heft 38 vom 19.09.2014, Seite A 1583.

(Directive of the federal chamber of physicians for quality assurance of medical laboratory investigation dated 11.04.2014 and 20.06.2014, Deutsches Ärzteblatt volume 111, issue 38, 19.09.2014, page A 1583).