

Deutsche Akkreditierungsstelle GmbH

Entrusted according to Section 8 subsection 1 AkkStelleG in connection with Section 1 subsection 1 AkkStelleGBV

Accreditation



The Deutsche Akkreditierungsstelle GmbH attests that the provider of proficiency testing schemes

Stiftung für Pathobiochemie und Molekulare Diagnostik
Referenzinstitut für Bioanalytik
Friedorfer 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 (incl. Hematology, Hemostaseology), Immunology, Microbiology, Virology, Humangenetics, Transfusion medicine

Using The Proficiency Testing Materials:

Blood, blood preparations, serum, plasma, hemolysate, urinary components, liquor, urine, aqueous solutions, gas-equilibrated solutions, lyophilized DNA-preparations, sputum samples, lyophilized bacteria strains; Cultivation tests, swab, stool smears, for the virtual microscopy; Smears-preparations for colouring and assessment.

The accreditation certificate shall only apply in connection with the notice of accreditation of 07.07.2017 with the accreditation number D-EP-15117-01 and is valid until 17.05.2020. It comprises the cover sheet, the reverse side of the cover sheet and the following annex with a total of 7 pages.

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

Frankfurt am Main,
07.07.2017

Dipl.-Biol. Uwe Zimmermann
Head of Division

Translation issued:
05.10.2017



Head of Division

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

See notes overleaf.

Deutsche Akkreditierungsstelle GmbH

Annex to the Accreditation Certificate D-EP-15117-01-00 according to DIN EN ISO/IEC 17043:2010

Period of validity: 07.07.2017 to 17.05.2020

Date of issue: 05.10.2017

Holder of certificate:

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

Proficiency testing in the following fields:

Medical Laboratory Diagnostics

Investigation Fields:

Clinical Chemistry (incl. Hematology, Hemostaseology), Immunolgy, Microbiology, Virology,
Human genetics, Transfusion medicine

Investigation Field: Clinical Chemistry

Testing field	Matrix / Products	Test parameters/ Analytes	Proficiency Testing schemes*
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)
Ciclosporin	hemolyzed blood	Ciclosporin, a. o.	Proficiency Test Ciclosporin (CS)
Cardiac markers	serum	CK-MB, Troponin, a. o.	Proficiency Test Cardiac markers (CM)
Drug screening	Urine	Amphetamines, Barbiturates, Benzodiazepines, Cannabinoides 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	lyophilized whole blood, Hemolysate	HbA1	Proficiency Test Glycated hemoglobin Determination HbA1c (GH)
Glucose "wet chemistry" and "dry chemistry"	serum	Glucose	Proficiency Test Glucose "wet chemistry" 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)
Clinical chemical analytes	cerebrospinal fluid (CSF)	glucose, lactat, total protein, L-albumin a. o.	Proficiency Test Clinical chemical analytes in cerebrospinal fluid (KL)

Testing field	Matrix / Products	Test parameters/ Analytes	Proficiency Testing schemes*
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)
Rheumatoid factors	serum	Rheumatoid factors, Anti-CCP-Ab, IgM-RF, IgG-RF a. o.	Proficiency Test Rheumatoid factors (RF)
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 a.o.	Proficiency Test Tumor markers (TM)
Carrier-bound reagents dry chemistry	serum	bilirubin total, cholesterol, glucose, uric acid, a. o.	Proficiency Test Carrier-bound reagents (Clinical chemical analytes in serum) dry chemistry (TR)

Testing field	Matrix / Products	Test parameters/ Analytes	Proficiency Testing schemes*
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)
Cytokines	serum	IL-6, IL-8, IL-10, TNF alpha, PCT a. o.	Proficiency Test Cytokines (ZY)
Cerebrospinal fluid cytospin preparation	exclusively web-based proficiency Test	assessment	Proficiency Test Cerebrospinal fluid cytospin preparation (ZZ)
Hematology			
Automatic differential count	whole blood	neutrophile granulocytes, lymphocytes, monocytes a. o.	Proficiency Test Automatic differential count (AD)
Differential blood count	smears, dyed	WB1-Morphology of leucocytes, blasts, promyelocytes a. o.	Proficiency Test Differential blood count (DF)
Small blood count	blood preparation	hemoglobin, erythrocytes, leukocytes a. o.	Proficiency Test Small Blood count (HA)
Immunophenotyping (flow cytometrie)	blood preparation	leukocyte count, lymphocyte count, CD3+ a. o.	Proficiency Test Immunophenotyping (flow cytometrie) (IS)
Retikulocytes	blood preparation	Retikulocytes relative and total	Proficiency Test Retikulocytes (RE)
Hemostaseology			
D-dimer	plasma	D-dimer	Proficiency Test D-dimer (DD)
Coagulation analysis	plasma	Prothrombin time (Quick), TPZ INR, aPTT, thrombin time (TZ/PTZ) a. o.	Proficiency Test Coagulation analysis (GR)

*exemplary list

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, 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)

*exemplary list

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 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)
Immunhämatologie Minor (basic program)	erythrozytes-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*
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)

Testing field	Matrix / Products	Test parameters/ Analytes	Proficiency Testing schemes*
Virus serology	serum, plasma	Anti-HCV 1/2 Ak / Ag(p24)	Proficiency Test HIV 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 (matrix)	Norovirus RNA	Proficiency Test Norovirus- PCR (NOROpqr)
Virus serology	serum, plasma	Anti-rubella virus IgG, IgM a.o.	Proficiency Test Anti-rubella virus (RoetLimm)

*exemplary list

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)

Testing field	Matrix / Products	Test parameters/ Analytes	Proficiency Testing schemes*
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 a.o.	Proficiency Test Anti- Toxoplasma gondii (ToxoGimm)
Infection serology	plasma, serum	Anti-Treponema pallidum IgG, IgM a.o.	Proficiency Test Anti- Treponema pallidum (TrepPimm)
Infection serology	plasma, serum	Anti-echinococcus, Anti-plasmodium, Anti- candida albicans a.o.	Proficiency Test Various Proficiency Test immunological analytes (VariAimm)
Infection serology	plasma, serum	Anti-Borrelia burgdorferi IgG, IgM a.o.	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, TubDiag2)=INSTAND 424, parasites (ToxoGen)

*exemplary list

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) a. o.	Proficiency Test DNA-isolation (DI)
Molecular biology	DNA-preparation	Faktor V (Leiden), Faktor II 20210, MTHFR, PAI-1 u. a.	Proficiency Test Molecular biology (FV)
DNA-sequencing	DNA-preparation	DNA-sequencing	Proficiency Test DNA-sequencing (SQ)

*exemplary list

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).