

Deutsche Akkreditierungsstelle

Annex to the Accreditation Certificate D-EP-19851-01-00 according to DIN EN ISO/IEC 17043:2023

Valid from: 05.03.2025

Date of issue: 05.03.2025

Holder of accreditation certificate:

ESfEQA GmbH
Siemensstraße 38, 69123 Heidelberg, Germany

with the location

ESfEQA GmbH
Siemensstraße 38, 69123 Heidelberg, Germany

The proficiency testing provider meets the requirements of DIN EN ISO/IEC 17043:2023 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-19851-01-00

Proficiency testing in the field of Medical Laboratory Diagnostics

Investigation Fields:

Clinical Chemistry
Microbiology
Virology
Transfusion medicine

*Within the given types of matrices/products and test parameters /analytes marked with * the proficiency testing provider is permitted, without being required to inform and obtain prior approval from DAkkS, to include of proficiency tests within the scope of accreditation.
The proficiency testing provider maintains a current list of all proficiency tests in a flexible scope of accreditation.*

Investigation Field: Clinical Chemistry

Testing field	Matrix/Products	Test parameters/ Analytes*	Proficiency Testing Programs*
Biochemistry	Serum, Plasma	Albumin, Alkaline Phosphatase, ALT/GPT, Amylase, Amylase pancreatic, AST/GOT, Bilirubin direct, Bilirubin total, Calcium, Calcium (ionized), Chloride, Cholesterol, Cholinesterase, Creatinkinase, Copper, Creatinine, Gamma GT, Glucose, HDL Cholesterol, Iron, Lactate, Lactate-Dehydrogenase, LDL Cholesterol, Lipase, Lithium, Magnesium, Phosphate, Potassium, Sodium, TIBC Total Iron Binding Capacity, Total Protein, Triglycerides, Urea, Uric Acid, Zinc	Clinical Chemistry (CC4, CC12)
Urin Chemistry	Urine	Albumin, Amylase, Calcium, Chloride, Creatinine, Glucose, Magnesium, Phosphate, Potassium, Total Protein, Sodium, Urea, Uric Acid	Urine Chemistry (UC)

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Testing field	Matrix/Products	Test parameters/ Analytes*	Proficiency Testing Programs*
Cardiac Marker	Serum, Plasma	BNP, CK-MB (mass), CK-MB (activity), Homocysteine, Myoglobin, NT-proBNP, Troponin I, Troponin T	Cardiac Marker (CM4, CM12)
Glycated Hemoglobin	Whole blood, hemolysate	HbA1c, Hemoglobin	Glycated Hemoglobin (GHB)
Ethanol, Ammonia and Bicarbonate	Aqueous solution	Ethanol, Ammonia, Bicarbonate	Ethanol, Ammonia and Bicarbonate (ETH)
Therapeutic Drug Monitoring	Serum, Plasma	Amikacin, Carbamazepine, Chinidine, Chloramphenicol, Digoxin, Disopyramid, Ethosuximid, Gentamicin, Lidocain, NAPA, Paracetamol, Phenobarbital, Phenytoin, Primidon, Procainamide, Salicylate, Theophylline, Tobramycin, Valproic acid, Vancomycin	Therapeutic Drugs (TDM)
Drugs of Abuse	Urine	Acetylmorphine, Amphetamines, Benzodiazepines, Buprenorphine, Cannabinoids, Cocaine, Barbiturates, Methadone, Opiates, Synthetic Cannabinoids (K2/Spice), Tricyclic Antidepressants	Drugs (of Abuse)
Urine Rapid Testing	Urine	Bilirubin, Glucose, HCG, Hemoglobin, Ketone, Leucocytes, Nitrite, pH, Specific Gravity, Total Protein, Urobilinogen	Qualitative Urine Analysis (US)
Urine Sediment	Urine	Bacteria, Casts, Crystals, RBC, WBC qualitative, semi-quantitative and quantitative	Urine Sediment (USEDL cytometric, USEDM microscopic)
Blood Gas	Aqueous solution	Calcium, Chloride, Glucose, Lactate, pCO ₂ , pH, pO ₂ , Potassium, Sodium, Urea	Blood Gas and Electrolytes (BG)

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Fecal Occult Blood	Aqueous Solution	Human Hemoglobin in faeces	Fecal Occult Blood (FOB)
Haemostaseology	Plasma	aPTT, Antithrombin III, D-Dimer, Fibrinogen, Prothrombin time, Protein C, Protein S	Coagulation (COA4, COA12)
Tumor Marker	Serum, Plasma	AFP, CEA, CA 19-9, CA 125, CA 15-3, CA 72-4, Cyfra 21-1, Ferritin, PSA total, PSA free, PSA complex	Tumor Marker (TM4, TM12, TMH4, TMH12)
Hormones	Serum, Plasma	Aldosterone, AMH, Androstendione, Calcitonin, C-Peptide, Cortisol, DHEA-S, Estradiol, Folate, FSH, hCG, Homocysteine, Human Growth Hormone, IgE, Insulin, LH, Methylmalonic acid, Estradiol, Progesterone, Prolactin, PTH, SHBG, Testosterone, Thyroglobulin, T3 free, T3 total, T4 free, T4 total, TSH, Vitamin B12, Vitamin D, 17-OH-Progesterone	Hormones (HOR4, HOR12, TMH4, TMH12, HCG)
hCG	Serum, Plasma	qualitative: hCG	HCG
Specific Proteins	Serum, Plasma	Albumin, Alpha-1-acid Glycoprotein, Alpha-1-Antitrypsin, Alpha-2-Macroglobulin, ASO, Beta-2-Microglobulin, C3, C4, Ceruloplasmin, CRP, Haptoglobin, IgA, IgE, IgG, IgM, Kappa light chains free, Lambda light chains free, Prealbumin, RF, Transferrin	Specific Proteins (SP4, SP12)
Thyroid antibodies	Serum, Plasma	Thyroglobulin antibodies (anti-TG), Thyroperoxidase antibodies (anti-TPO), TSH receptor antibodies (TRAb)	Thyroid antibodies (ANTI-THYR)
Procalcitonin	Serum	Procalcitonin	PCT
Haematology	Whole Blood	HGB, HCT, MCH, MCHC,	Hemogram (HEM4,

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		MCV, PLT, RBC, WBC, RDW, MPV	HEM12)
Haematology	Whole Blood	HGB, HCT, MCH, MCHC, MCV, PLT, RBC, WBC, RDW, MPV, LYMPH %, LYMPH, MID %, MID, MONO %, MONO, MXD %, MXD, NEUT %, NEUT	Hemogram incl. 3-part Diff. (HEM3D)
Erythrocyte Sedimentation Rate	Whole Blood	ESR	ESR

Investigation Field: Microbiology

Testing field	Matrix/Products	Test parameters/ Analytes*	Proficiency Testing Programs*
Serology	Plasma	qualitative: Antibodies against Treponema pallidum, Non- Treponemal (lipoid) Antibodies	Syphilis (SYP)
Serology	Plasma	qualitative: Antibodies against Trypanosoma cruzi	Chagas (CHA)
Serology	Plasma	qualitative: Antibodies (IgG, IgM, IgA) against Chlamydia pneumoniae	Chlamydia pneumoniae (CHP)
Serology	Plasma	qualitative: Antibodies (IgG, IgM, IgA) against Chlamydia trachomatis	Chlamydia trachomatis (CHT)
Serology	Plasma	qualitative: Antibodies (IgG, IgM) against Borrelia	Borrelia (BOR)
Bacteriology	Lyophilized bacteria strains	Identification (genus and species), Antibiotic susceptibility testing	Bacteriology (BAC)
Serology	Plasma	qualitative: Antibodies (IgG, IgM, IgA) against Brucella, Agglutinating Antibodies against Brucella	Brucella (BRU)
Serology	Plasma	qualitative: Antibodies (IgG, IgM) against Leptospira	Leptospira (LEP)

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Investigation field: Virology

Testing field	Matrix/Products	Test parameters/ Analytes*	Proficiency Testing Programs*
Serology	Plasma	qualitative: anti-HAV IgG + total, anti-HAV IgM	Hepatitis A Virus (HAV)
Serology	Plasma	qualitative: anti-HBs, anti-HBc, anti-HBe, HBeAg, anti-HBc IgM qualitative and quantitative: HBsAg	Hepatitis B Virus (HBV)
Serology	Plasma	qualitative: anti-HIV 1/2, anti-HCV, anti-HBc, HBsAg	Infectious Disease Combination Control (INF)
Serology	Plasma	qualitative: anti-VZV IgG + total, anti-VZV IgM, anti-VZV IgA	Varicella Zoster Virus (VZV)
Serology	Plasma	qualitative: anti-EBV VCA IgG + total, anti-EBV EBNA-1 IgG + total, anti-EBV VCA IgM	Epstein-Barr Virus (EBV)
Serology	Plasma	qualitative: anti-Rubella IgG + total, anti-Rubella IgM, anti-CMV IgG + total, anti-CMV IgM, anti-HSV 1/2 IgG + total, anti-HSV 1/2 IgM	ToRCH (TORCH)
Serology	Plasma	qualitative: antibodies (IgG, IgM) against Parvovirus B19	Parvovirus B19 (PAR)
Serology	Plasma	qualitative: antibodies (IgG, IgM) against Measles virus	Masern (MEA)
Serology	Plasma	qualitative: anti HTLV I/II	HTLV I/II (HTL)
Serology	Plasma	qualitative: anti-HEV (IgG, IgM)	Hepatitis E Virus (HEV)
Serology	Plasma	qualitative: anti-Chikungunya virus (IgG, IgM)	Chikungunya virus (CHIKV); Mosquito-transmitted Diseases (MTD)
Serology	Plasma	qualitative: anti-Dengue virus (IgG, IgM)	Dengue virus (DENV); Mosquito-transmitted Diseases (MTD)
Serology	Plasma	qualitative: anti-West Nile Virus (IgG, IgM)	West Nile Virus (WNV); Mosquito-transmitted Diseases (MTD)

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Serology	Plasma	qualitative: anti-Zika Virus (IgG, IgM)	Zika Virus (ZIKV); Mosquito-transmitted Diseases (MTD)
Serology	Plasma	Qualitative: IgA, IgG, IgM and total Antibodies against SARS-CoV-2	SARS-CoV-2 Antibodies (COVID)
Antigen detection	Aqueous solution (lyophilised)	qualitative: SARS-CoV-2 Antigen	SARS-CoV-2 Antigen (COVAG)
Molecular biology	Aqueous solution (lyophilised)	qualitative: SARS-CoV-2 RNA	SARS-CoV-2 Molecular (COVM)

Investigation Field: Transfusion medicine

Testing field	Matrix/Products	Test parameters/ Analytes	Proficiency Testing Programs ¹
Immunohaematology	Erythrocyte suspension, Serum, Whole Blood	ABO-Typing, A subgroups, Rh-Factor D, Rh-Typing, Kell antigen, Direct Coombs Test, Irregular antibodies (antibody screening/Indirect Coombs Test), Antibody identification, Compatibility testing (cross-matching)	Immunohaematology (IMHEM)
Immunohaematology	Erythrocyte suspension, Serum, Whole Blood	ABO-Typing, Rh-Factor D	Blood grouping (ABO)

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

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