

Deutsche Akkreditierungsstelle GmbH

Annex to the Accreditation Certificate D-EP-19851-01-00 according to DIN EN ISO/IEC 17043:2010

Period of validity: 24.08.2018 to 21.01.2021

Date of issue: 31.08.2018

Holder of certificate:

ESfEQA GmbH
Siemensstraße 38, 69123 Heidelberg

Proficiency testing in the following fields:

Medical Laboratory Diagnostics

Investigation Fields:

Clinical Chemistry, Virology, Microbiology

Using The Proficiency Testing Materials:

Whole blood, serum, plasma, urine, hemolysate, lyophilized bacteria and aqueous solutions

Abbreviations used: see last page

Investigation Field: Clinical Chemistry

Testing field	Matrix / Products	Test parameters/ Analytes	Proficiency Testing schemes
Biochemistry	Serum Plasma	Albumin, Alkaline Phosphatase, ALT/GPT, Amylase, AST/GOT, Bilirubin direct, Bilirubin total, Calcium, Calcium (ionized), Chloride, Cholesterol, Creatinkinase, 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	Clinical Chemistry (CC4, CC12)
Urin Diagnostics	Urine	Albumin, Calcium, Chloride, Creatinine, Glucose, Magnesium, Phosphate, Potassium, Total Protein, Sodium, Urea, Uric Acid	Urine Chemistry (UC)
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	Aqueous solution	Ethanol, Ammonium-hydroxide	Ethanol (ETH)
Pharmaceuticals	Serum Plasma	Amikacin, Carbamazepine, Chinidine, Chloramphenicol, Digoxin, Disopyramid, Ethosuximid, Gentamicin, Lidocain NAPA, Paracetamol, Phenobarbital, Phenytoin, Primidon, Procainamide, Salicylate, Theophylline, Tobramycin, Valproinacid, Vancomycin	Therapeutic Drugs (TDM)
Drugs of Abuse	Urine	Acetylmorphine,	Drugs (DAT)

Testing field	Matrix / Products	Test parameters/ Analytes	Proficiency Testing schemes
		Amphetamines, Benzo- diazepines, Buprenor- phines, Cannabinoids, Cocaine, Barbiturates, Methadone, Opiates, Tricyclic Antidepressants	
Urine Rapid Tests	Urine	Bilirubin, Glucose, Hemoglobin, Ketone(bodies), Leucocytes, Nitrite, pH, Specific Gravity, Total Protein, Urobilinogen	Qualitative Urine Analysis (US)
Blood Gas	Aqueous solution	Calcium, Chloride, Glu- cose, Lactate, pCO ₂ , pH, pO ₂ , Potassium, Sodium, Urea	Blood Gas and Electrolytes (BG)
Lipids	Serum, Plasma	Apolipoprotein A1, Apo- lipoprotein B, LDL-Choles- terol, Cholesterol, Tri- glycerides, HDL-Choles- terol, Lp (a), Total Protein	Lipids (LIP)
Fecal Diagnostics (Occult Blood)	Aqueous Solution	Human Haemoglobin in faeces	Fecal Occult Blood (FOB)
Coagulation	Plasma	aPTT, Antithrombin III, D- Dimer, Fibrinogen, Pro- thrombin 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	Tumormarker (TM4, TM12, TMH4, TMH12)
Hormones	Serum Plasma	Aldosterone, AMH, Andro- stendione, Calcitonin, C- Peptid, Cortisol, DHEA-S, Estriol, Folate, FSH, hCG, human growth hormone, IgE, Insulin, LH, Estradiol, Progesterone, Prolactin, PTH, SHBG, Testosterone, Thyreoglobulin, T3 free, T3 total, T4 free, T4 total, TSH, Vitamin B12, Vitamin D	Hormones (HOR4, HOR12, TMH4, TMH12)
Spezific Proteins	Serum	Albumin, Alpha-1-acid	Specific Proteins (SP4,

Testing field	Matrix / Products	Test parameters/ Analytes	Proficiency Testing schemes
	Plasma	Glykoprotein, Alpha-1-Antitrypsin, Alpha-2-Macroglobulin, ASO, Beta-2-Microglobulin, C3, C4, Ceruloplasmin, CRP, Haptoglobin, IgA, IgE, IgG, IgM, Prealbumin, RF, Transferrin	SP12)
Hemogram	Whole Blood	HGB, HCT, MCH, MCHC, MCV, PLT, RBC, WBC, RDW, MPV	Hemogram (HEM4, HEM12)

Investigation field: Virology

Testing field	Matrix / Products	Test parameters / Analytes	Proficiency Testing Programs
Serology	Plasma	anti-CMV IgG + total, anti-CMV IgM	Cytomegalovirus (CMV)
Serology	Plasma	anti-HAV IgG + total, anti-HAV IgM	Hepatitis A Virus (HAV)
Serology	Plasma	anti-HBs, anti-HBc, anti-HBe, HBsAg (qual. und quant.), HBeAg, anti-HBc IgM	Hepatitis B Virus (HBV)
Serology	Plasma	anti-HIV 1/2, anti-HCV, anti-HBc, HBsAg	Infectious Disease Combination Control (INF)
Serology	Plasma	anti-HSV 1/2 IgG + total, anti-HSV 1/2 IgM	Herpes Simplex Virus (HSV)
Serology	Plasma	anti-Rubella IgG + total, anti-Rubella IgM	Rubella (RUB)
Serology	Plasma	anti-VZV IgG + total, anti-VZV IgM	Varicella Zoster Virus (VZV)
Serology	Plasma	anti-EBV VCA IgG + total, anti-EBV EBNA-1 IgG + total, anti-EBV VCA IgM	Epstein-Barr Virus (EBV)
Serology	Plasma	anti-Rubella IgG + total (qual.), anti-Rubella IgM, anti-CMV IgG + total (qual.), anti-CMV IgM, anti-HSV 1/2 IgG + total (qual.), anti-HSV 1/2 IgM	ToRCH (TORCH)

Testing field	Matrix / Products	Test parameters / Analytes	Proficiency Testing Programs
Serology	Plasma	Antibodies (IgG, IgM) against Parvovirus B19	Parvovirus B19 (PAR)
Serology	Plasma	Antibodies (IgG, IgM) against Measles virus	Masern (MEA)
Serology	Plasma	anti HTLV I/II	HTLV I/II (HTL)

Investigation Field: Mikrobiology

Testing field	Matrix / Products	Test parameters / Analytes	Proficiency Testing Programs
Serology	Plasma	anti-Toxoplasmosis IgG + total, anti-Toxoplasmosis IgM	Toxoplasmose, (TORCH)
Serology	Plasma	Antibodies against Treponema pallidum	Syphilis (SYP)
Serology	Plasma	Antibodies (IgG, IgM, IgA) against Chlamydia pneumoniae	Chlamydia pneumoniae (CHP)
Serology	Plasma	Antibodies (IgG, IgM, IgA) against Chlamydia trachomatis	Chlamydia trachomatis (CHT)
Serology	Plasma	Antibodies (IgG, IgM) against Borrelia	Borrelia (BOR)
Bakteriologie	Lyophilized bacteria strains	Identification (genus and species), Antibiotic susceptibility testing	Bacteriology (BAC)
Serology	Plasma	Antibodies (IgG, IgM, IgA) against Brucella	Brucella (BRU)
Serology	Plasma	Antibodies (IgG, IgM) against Leptospira	Leptospira (LEP)