

Deutsche Akkreditierungsstelle GmbH

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

Period of validity: 10.04.2017 to 21.01.2021

Date of issue: 10.04.2017

Holder of certificate:

ESfEQA GmbH
Siemensstraße 38, 69123 Heidelberg

Proficiency testing in the following fields:

Medical Laboratory Diagnostics

Investigation Fields:

Clinical Chemistry, Virology

Using the proficiency testing materials:

Whole blood, serum, plasma, urine, hemolysate and aqueous solution

Investigation Field: Clinical Chemistry

Testing field	Matrix / Products	Test parameters/ Analytes	Proficiency Testing Programs
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)
Urine Chemistry	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)
Therapeutic drug monitoring	Serum Plasma	Amikacin, Carbamazepine, Chinidine, Chloramphenicol, Digoxin, Disopyramide, Ethosuximide, Gentamicin, Lidocain, NAPA, Paracetamol, Pheno-barbital, Phenytoin, Primidone, Procainamide, Salicylate, Theophylline, Tobramycin, Valproic Acid, Vancomycin	Therapeutic Drugs (TDM)

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Testing field	Matrix / Products	Test parameters/ Analytes	Proficiency Testing Programs
Drugs of abuse	Urine	Acetylmorphine, Amphetamines, Benzodiazepines, Buprenorphine, Cannabinoids, Cocaine, Barbiturates, Methadone, Opiates, Tricyclic Antidepressants	Drugs of Abuse (DAT)
Urine rapid testing	Urine	Bilirubin, Glucose, Hemoglobin, Ketone bodies, Leucocytes, Nitrite, pH, Specific Gravity, Total Protein, Urobilinogen	Qualitative Urine Analysis (US)
Blood gas	Aqueous solution	Calcium, Chloride, Glucose, Lactate, pCO ₂ , pH, pO ₂ , Potassium, Sodium, Urea	Blood gas and electrolytes (BG)
Lipids	Serum Plasma	Apolipoprotein A1, Apolipoprotein B, LDL-Cholesterol, Cholesterol, Triglycerides, HDL-Cholesterol, Lp (a), Total Protein	Lipids (LIP)
Fecal occult blood	Aqueous solution	Human hemoglobin in faeces	Fecal Occult Blood (FOB)
Coagulation	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, Calcitonine, C-Peptide, Cortisol, DHEA-S, Estriol, Folate, FSH, hCG, hGH, human growths 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)

Testing field	Matrix / Products	Test parameters/ Analytes	Proficiency Testing Programs
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, Prealbumin, RF, Transferrin	Specific Proteins (SP4, 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
Virus immunology	Plasma	anti-CMV IgG + total, anti-CMV IgM	Cytomegalovirus (CMV)
Virus immunology	Plasma	anti-HAV IgG + total, anti-HAV IgM	Hepatitis A Virus (HAV)
Virus immunology	Plasma	anti-HBs, anti-HBc, anti-HBe, HBsAg (qual. and quant.), HBeAg, anti-HBc IgM	Hepatitis B Virus (HBV)
Virus immunology	Plasma	anti-HIV 1/2, anti-HCV, anti-HBc, HBsAg	Infectious Disease Combination Control (INF)
Virus immunology	Plasma	anti-HSV 1/2 IgG + total, anti-HSV 1/2 IgM	Herpes Simplex Virus (HSV)
Virus immunology	Plasma	anti-Toxoplasmosis IgG + total, anti-Toxoplasmosis IgM	Toxoplasmosis (TOX)
Virus immunology	Plasma	anti-Rubella IgG + total, anti-Rubella IgM	Rubella (RUB)
Virus immunology	Plasma	anti-VZV IgG + total, anti-VZV IgM	Varicella Zoster Virus (VZV)
Virus immunology	Plasma	anti-Treponema pallidum antibodies	Syphilis (SYP)
Virus immunology	Plasma	anti-EBV VCA IgG +total, anti-EBV EBNA IgG + total, anti-EBV VCA IgM	Epstein-Barr Virus (EBV)

Testing field	Matrix / Products	Test parameters/ Analytes	Proficiency Testing Programs
Virus immunology	Plasma	anti-Toxoplasmosis IgG + total, anti-Toxoplasmosis IgM, 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)
Virus immunology	Plasma	antibodies (IgG, IgM, and IgA) against Chlamydia pneumoniae	Chlamydia pneumoniae (CHP)
Virus immunology	Plasma	antibodies (IgG, IgM, and IgA) against Chlamydia trachomatis	Chlamydia trachomatis (CHT)
Virus immunology	Plasma	antibodies (IgG and IgM) against Parvovirus B19	Parvovirus B19 (PAR)
Virus immunology	Plasma	antibodies (IgG and IgM) against Measles virus	Measles (MEA)
Virus immunology	Plasma	antibodies (IgG and IgM) against Borrelia	Borrelia (BOR)

Statistical evaluation:

ISO 13528:2015 (E): Statistical methods for use in proficiency testing by interlaboratory comparisons (second edition 2015-08-01)