

Deutsche Akkreditierungsstelle GmbH

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

Valid from: 17.03.2020

Date of issue: 17.03.2020

Holder of certificate:

ESfEQA GmbH
Siemensstraße 38, 69123 Heidelberg

Proficiency testing in the fields:

Medical Laboratory Diagnostics

Investigation Fields:

Clinical Chemistry, Microbiology, Virology

Using the proficiency testing materials:

Whole blood, serum, plasma, urine, hemolysate, lyophilized bacteria strains and aqueous solution.

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

Abbreviations used: see last page

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>

Investigation Field: Clinical Chemistry

Testing field	Matrix / Products	Test parameters / Analytes	Proficiency Testing Programs ¹
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, 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, Ammonia	Ethanol (ETH)

-Translation-

Testing field	Matrix / Products	Test parameters / Analytes	Proficiency Testing Programs ¹
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	Drogen (DAT)
Urine Rapid Testing	Urine	Bilirubin, Glucose, HCG, Hemoglobin, Ketone, 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 Haemoglobin in faeces	Fecal Occult Blood (FOB)

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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	Tumormarker (TM4, TM12, TMH4, TMH12)
Hormones	Serum Plasma	Aldosterone, AMH, Androstendione, Calcitonin, C-Peptid, Cortisol, DHEA-S, Estriol, Folate, FSH, hCG, Homocystein, human growth hormone, IgE, Insulin, LH, Methylmalonic acid, Estradiol, Progesterone, Prolactin, PTH, SHBG, Testosterone, Thyreoglobulin, T3 free, T3 total, T4 free, T4 total, TSH, Vitamin B12, Vitamin D, 17-OH-Progesterone	Hormones (HOR4, HOR12, TMH4, TMH12)
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)
Procalcitonin	Serum	Procalcitonin	PCT

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Hemogram	Whole Blood	HGB, HCT, MCH, MCHC, MCV, PLT, RBC, WBC, RDW, MPV	Hemogram (HEM4, HEM12)
Hemogram	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

¹ exemplary list

Investigation Field: Microbiology

Testing field	Matrix / Products	Test parameters / Analytes	Proficiency Testing Programs ¹
Serology	Plasma	qualitative: Antibodies against <i>Treponema pallidum</i>	Syphilis (SYP)
Serology	Plasma	qualitative: Antibodies against <i>Trypanosoma cruzi</i>	Chagas (CHA)
Serology	Plasma	qualitative: Antibodies (IgG, IgM, IgA) against <i>Chlamydia pneumoniae</i>	Chlamydia pneumoniae (CHP)
Serology	Plasma	qualitative: Antibodies (IgG, IgM, IgA) against <i>Chlamydia trachomatis</i>	Chlamydia trachomatis (CHT)
Serology	Plasma	qualitative: Antibodies (IgG, IgM) against <i>Borrelia</i>	Borrelia (BOR)
Bacteriology	Lyophilized bacteria strains	Identification (genus and species), Antibiotic susceptibility testing	Bacteriology (BAC)
Serology	Plasma	qualitative: Antibodies (IgG, IgM, IgA) against <i>Brucella</i>	Brucella (BRU)
Serology	Plasma	qualitative: Antibodies (IgG, IgM) against <i>Leptospira</i>	Leptospira (LEP)

¹ exemplary list

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Investigation field: Virology

Testing field	Matrix / Products	Test parameters / Analytes	Proficiency Testing Programs ¹
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	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-Chikungunyavirus (IgG, IgM)	Chikungunyavirus (CHIKV); Mosquito-transmitted Diseases (MTD)
Serology	Plasma	qualitative: anti-Denguevirus (IgG, IgM)	Denguevirus (DENV); Mosquito-transmitted Diseases (MTD)

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Testing field	Matrix / Products	Test parameters / Analytes	Proficiency Testing Programs¹
Serology	Plasma	qualitative: anti-West-Nile-Virus (IgG, IgM)	West-Nile-Virus (WNV); Mosquito-transmitted Diseases (MTD)
Serology	Plasma	qualitative: anti-Zika Virus (IgG, IgM)	Zika Virus (ZIKV); Mosquito-transmitted Diseases (MTD)

¹ exemplary list

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