

Deutsche Akkreditierungsstelle GmbH

Annex to the Accreditation Certificate D-PL-19275-01-00 according to DIN EN ISO/IEC 17025:2018

Valid from: 21.01.2020

Date of issue: 06.08.2020

Holder of certificate:

EXcorLab GmbH

Industrie Center Obernburg, 63784 Obernburg

Tests in the field:

Health care (medical laboratory tests in the context of clinical studies)

Testing Area:

Clinical chemistry

For the tests marked with * the laboratory is permitted to select standardised or equivalent test methods without prior notification and consent from the Deutsche Akkreditierungsstelle GmbH (DAkkS GmbH).

For the tests marked with ** the laboratory is permitted to modify and develop new test procedures without obtaining prior notification and consent from the Deutsche Akkreditierungsstelle GmbH (DAkkS GmbH). The specified test procedures are examples. The laboratory has an actual list of all test procedures in the flexible field of accreditation available.

*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 (DAkkS).
<https://www.dakks.de/en/content/accredited-bodies-dakks>*

Testing Area: Clinical chemistry

Type of test:

Flow cytometry**

Analyte (measurement parameter)	Test material (matrix)	Test method
Apoptose / Annexin V	Blood, cell culture	Flow cytometry
CR3 (CD11b/CD18)	Blood	Flow cytometry
Oxidative burst	Blood	Flow cytometry
Neutrophil activation	Blood	Flow cytometry
Monocyte subpopulations	Blood	Flow cytometry
BD Leucocount	Plasma/Blood	Flow cytometry
TBNK-Lymphocyte subpopulations	Blood	Flow cytometry
BD Plasma count (residual cells)	Plasma/Blood	Flow cytometry
Dendritic cells	Blood	Flow cytometry
Platelet activation PAC-1/CD62P	Blood	Flow cytometry
Blood cells: -Platelets -red cells -Leukocytes -Hematocrit -Hemoglobin	Blood	Particle / Cell count by impedance method (determination of resistance)

Type of test:

Electrochemical tests**

Analyte (measurement parameter)	Test material (matrix)	Test method
Sodium	Blood, Plasma, Serum, Aqueous solutions	Potentiometry
Potassium	Blood, Plasma, Serum, Aqueous solutions	Potentiometry
Chlorine	Blood, Plasma, Serum, Aqueous solutions	Potentiometry
Calcium	Blood, Plasma, Serum, Aqueous solutions	Potentiometry
pH	Blood, Plasma, Serum, Aqueous solutions	Potentiometry
PO ₂	Blood	Amperometry
PCO ₂	Blood	Potentiometry

Type of test:

Electrophoresis**

Analyte (measurement parameter)	Test material (matrix)	Test method
Relative molecular weight of proteins	Plasma, Serum, Hemofiltrate, Physiological solutions	SDS Gel electrophoresis
Proteins	Plasma, Serum, Hemofiltrate, Physiological solutions	Gel electrophoresis (IEF / 2-D PAGE)

Type of test:

High performance liquid chromatography (HPLC)**

Analyte (measurement parameter)	Test material (matrix)	Test method
Amino acids	Plasma, Serum	HPLC (FD)
Indoxyl sulphate	Plasma, Serum, Aqueous solutions	HPLC (FD)
p-Cresyl sulphate	Plasma, Aqueous solutions	HPLC (FD)

Type of test:

Ligand assays**

Analyte (measurement parameter)	Test material (matrix)	Test method
Bisphenol A (BPA)	Plasma, Serum	ELSIA
Bradykinin	Plasma	ELISA
Interleukin-1 β	Plasma	ELISA
Interleukin-6	Plasma	ELISA
C3a, C5a, sC5b-9	Plasma	ELISA
Leptin	Plasma	ELISA
Myeloperoxidase (MPO)	Plasma	ELISA
ox LDL	Plasma	ELISA
Platelet factor 4 (PF4)	Plasma	ELISA
PMN Elastase	Plasma	ELISA
Thrombin-Antithrombin III-Complex (TAT)	Plasma	ELISA
TNF- α	Plasma	ELISA
Factor V	Plasma	ELISA
Factor X	Plasma	ELISA
Protein C	Plasma	ELISA

Type of test:

Microscopy**

Analyte (measurement parameter)	Test material (matrix)	Test method
Red cells	Blood smear	Microscopy (staining and microscopic evaluation)

Type of test:

Spectrometry (UV-/VIS-Photometry)**

Analyte (measurement parameter)	Test material (matrix)	Test method
Calcium	Plasma, Serum	Photometry
Cholesterol	Plasma, Serum, Aqueous solutions	Photometry
Creatinine	Plasma, Serum, Aqueous solutions	Photometry
Factor VIII	Plasma	Photometry
Glucose	Plasma, Serum	Photometry
Hemoglobin	Plasma, Serum	Photometry
Urea	Plasma, Serum, Aqueous solutions	Photometry
HDL-Cholesterol	Plasma, Serum, Aqueous solutions	Photometry

Analyte (measurement parameter)	Test material (matrix)	Test method
Heparin	Plasma, Aqueous solutions	Photometry
Inulin	Plasma, Aqueous solutions	Photometry
Lactate	Plasma, Serum	Photometry
LDL- Cholesterol	Plasma, Serum, Aqueous solutions	Photometry
Phosphate	Plasma, Serum, Aqueous solutions	Photometry
Total protein	Plasma, Serum, Aqueous solutions	Photometry
Triglycerides	Plasma, Serum, Aqueous solutions	Photometry
Vitamin B12	Plasma, Aqueous solutions	Photometry
Total protein (BCA)	Plasma, Aqueous solutions	Photometry
DEHP equivalents	Aqueous solutions	Photometry

Type of test:

Spectrometrie (Nephelometry)**

Analyte (measurement parameter)	Test material (matrix)	Test method
ADNase B	Plasma, Serum	Nephelometry
Albumin	Plasma, Serum, Aqueous solutions (Urine)	Nephelometry
Antistreptolysine (ASL)	Plasma, Serum	Nephelometry
Antithrombin III	Plasma	Nephelometry
α 1-Antitrypsin	Plasma, Serum	Nephelometry
Apolipoprotein A-I	Plasma, Serum	Nephelometry
Apolipoprotein A-II	Plasma, Serum	Nephelometry
Apolipoprotein B	Plasma, Serum	Nephelometry
Apolipoprotein E	Plasma, Serum	Nephelometry
C1-Inhibitor	Plasma, Serum	Nephelometry
Carbohydrate-deficient transferrin	Plasma, Serum	Nephelometry
Coeruloplasmin	Plasma, Serum	Nephelometry
C-reaktive protein (CRP)	Plasma, Serum	Nephelometry
Cystatin C	Plasma, Serum, Aqueous solutions	Nephelometry
Ferritin	Plasma, Serum	Nephelometry
Fibrinogen	Plasma	Nephelometry
Fibronectin	Plasma	Nephelometry
Hemopexin	Plasma, Serum	Nephelometry
Haptoglobin	Plasma, Serum	Nephelometry
Homocysteine	Plasma, Serum	Nephelometry
Free Ig/L chain (FLC), type kappa	Plasma, Serum, Aqueous solutions (Urine)	Nephelometry
Free Ig/L chain (FLC), type lamda	Plasma, Serum, Aqueous solutions (Urine)	Nephelometry
Immunoglobulin A (IgA)	Plasma, Serum	Nephelometry
Immunoglobulin E (IgE)	Plasma, Serum	Nephelometry
Immunoglobulin G (IgG)	Plasma, Serum, Aqueous solutions (Urine)	Nephelometry

Analyte (measurement parameter)	Test material (matrix)	Test method
Immunoglobulin M (IgM)	Plasma, Serum, Aqueous solutions	Nephelometry
Complement factor C3c	Plasma, Serum	Nephelometry
Complement factor C4	Plasma, Serum	Nephelometry
Lipoprotein (a)	Plasma, Serum	Nephelometry
Soluble transferrin receptor	Plasma, Serum	Nephelometry
α 2-macroglobulin	Plasma, Serum, Aqueous solutions (Urine)	Nephelometry
β 2-microglobulin	Plasma, Serum, Aqueous solutions (Urine)	Nephelometry
α 1-microglobulin	Plasma, Serum, Aqueous solutions (Urine)	Nephelometry
Myoglobin	Plasma, Serum, Aqueous solutions	Nephelometry
Plasminogen	Plasma	Nephelometry
Prealbumin	Plasma, Serum	Nephelometry
Retinol-binding protein (RBP)	Plasma, Serum	Nephelometry
Rheumatoid Factor (RF)	Plasma, Serum	Nephelometry
α 1-acidic Glycoprotein	Plasma, Serum	Nephelometry
Plasma, Serum Amyloid A Protein (SAA)	Plasma, Serum	Nephelometry
Transferrin	Plasma, Serum	Nephelometry

Type of test:

Spectrometry (Turbidimetry)*

Analyte (measurement parameter)	Test material (matrix)	Test method
Endotoxin	Aqueous solutions	Turbidimetry

Type of test:

Spectrometry (Fluorescence spectrometry)**

Analyte (measurement parameter)	Test material (matrix)	Test method
Cytotoxicity	Extracts / Aqueous solutions	Fluorimetry