

Deutsche Akkreditierungsstelle GmbH

Annex to the Accreditation Certificate D-PL-13334-01-00 according to DIN/IEC EN ISO 17025:2018

Valid from: 07.01.2022

Date of issue: 07.01.2022

Holder of certificate:

LKF Laboratorium für Klinische Forschung GmbH
Lise-Meitner-Strasse 25-29, 24223 Schwentinental

Tests in the field:

Health Care (medical laboratory examinations in the context of clinical studies)

Test areas:

Clinical chemistry

Immunology

Microbiology

Virology

Within the given type of examination marked with *), the testing laboratory is permitted, without being required to inform and obtain prior approval from DAkkS, the free choice of standards or equivalent examination procedures. Within the given type of examination marked with **), the testing laboratory is permitted, without being required to inform and obtain prior approval from DAkkS, the modification, development and refinement of examination procedures. The listed examination procedures are exemplary. The testing laboratory maintains a current list of all examination procedures within the flexible scope of accreditation

This document is a translation. The definitive version is the original German annex to the accreditation certificate. The management system requirements of DIN EN ISO/IEC 17025 are written in the language relevant to the operations of testing laboratories. Laboratories that conform to the requirements of this standard, operate generally in accordance with the principles of DIN EN ISO 9001. 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>

Test area: Clinical chemistry

Type of test:

Spectrometry (UV-/VIS-photometry)*

Analyte (measurement parameter)	Test material (matrix)	Test technique
1,5-Anhydroglucitol	Serum	Chromogenic Substrate
Albumin	Serum	Photometry
Alkaline Phosphatase	Serum	Photometry
Amylase	Serum	Photometry
Antithrombin III (activity)	Citrate Plasma	Chromogenic Substrate
Bicarbonate	Serum	Photometry
Bilirubin direct	Serum	Photometry
Bilirubin total	Serum	Photometry
Calcium	Serum/Urine	Photometry
Cholesterol	Serum	Photometry
Cholesterol-HDL direct	Serum	Photometry
Cholesterol-LDL direct	Serum	Photometry
Cholinesterase	Serum	Photometry
CK NAC-aktiviert	Serum	Photometry
CK-MB NAC-aktiviert	Serum	Photometry
Creatinine (enzymatisch)	Serum/Urine	Photometry
Creatinine (Jaffé)	Serum/Urine	Photometry
Iron	Serum	Photometry
Free fatty acids	Serum	Photometry
Free Hemoglobin	Heparin-/EDTA-Plasma	Photometry
Fructosamine	Serum	Photometry
Gamma-GT	Serum/Urine	Photometry
Coagulation Factor VIII	Citrate Plasma	Chromogenic Substrate
Coagulation Factor IX	Citrate Plasma	Chromogenic Substrate
GLDH	Serum	Photometry
Glucose	Hemolysate	Photometry
Glucose	Serum/Plasma/Urine	Photometry
GOT (ASAT)	Serum	Photometry
GPT (ALAT)	Serum	Photometry
Uric acid	Serum/Urine	Photometry
Urea Nitrogen	Serum/Urine	Photometry
HBDH	Serum	Photometry
LDH	Serum	Photometry
Lipase	Serum	Photometry
Lithium	Serum	Photometry
Magnesium	Serum/Urine	Photometry
N-Acetyl- β -D-glucosaminidase (β -NAG)	Urine	Photometry
P-Amylase	Serum	Photometry
Phosphate (inorg.)	Serum/Urine	Photometry
Protein C (activity)	Citrate Plasma	Chromogenic Substrate
Protein, total	Serum	Photometry
Triglyceride	Serum	Photometry
Valproic acid	Serum	Photometry

Type of test:
Spectrometry (nephelometry)*

Analyte (measurement parameter)	Test material (matrix)	Test technique
alpha2-Makroglobulin	Serum/Urine	Immunonephelometry
Cystatin C	Serum/Urine	Immunonephelometry
Haptoglobin	Serum	Immunonephelometry
Lipoprotein (a)	Serum	Immunonephelometry
Saures-alpha1-Glykoprotein	Serum	Immunonephelometry
Transferrin	Serum/Urine	Immunonephelometry

Type of test:
Spectrometry (reflectometry/carrier test methods)*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Bilirubin	Urine	Reflectometry
Erythrocytes	Urine	Reflectometry
Glucose	Urine	Reflectometry
Hemoglobin	Urine	Reflectometry
Ketone	Urine	Reflectometry
Leucocytes	Urine	Reflectometry
Nitrite	Urine	Reflectometry
pH	Urine	Reflectometry
Protein	Urine	Reflectometry
Spezific Weight	Urine	Reflectometry
Urobilinogen	Urine	Reflectometry

Type of test:
Spectrometry (turbidimetry/ immunoturbidimetry)*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Albumin	Urine	Immunoturbidimetry
alpha1-Microglobulin	Urine	Immunoturbidimetry
Apolipoprotein A 1	Serum	Immunoturbidimetry
Apolipoprotein B	Serum	Immunoturbidimetry
CRP	Serum	Immunoturbidimetry
Lipoprotein (a)	Serum	Immunoturbidimetry
HbA1c	Whole Blood	Immunoturbidimetry
Protein	Urine	Turbidimetry
Transferrin	Serum	Turbidimetry

Type of test:
Electrochemical tests*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Chloride	Serum/Urine	Potentiometry (ISE)
Potassium	Serum/Urine	Potentiometry (ISE)
Sodium	Serum/Urine	Potentiometry (ISE)

Type of test:
Flow cytometry*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Cellular Blood Count (incl. Diff.)	EDTA-Blood	Flow Cytometry
Cellular Blood Count	EDTA-Blood	Flow Cytometry
Differential Blood Count, autom.	EDTA-Blood	Flow Cytometry
NRBC (nucleated erythrocyte precursors)	EDTA-Blood	Flow Cytometry
Reticulocytes	EDTA-Blood	Flow Cytometry
Reticulocytes Hemoglobin	EDTA-Blood	Flow Cytometry
Thrombocytes	EDTA-Blood	Flow Cytometry

Type of test:
Coagulometry*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Fibrinogen	Citrate Plasma	Coagulometry
Coagulation Factor II	Citrate Plasma	Coagulometry
Coagulation Factor V	Citrate Plasma	Coagulometry
Coagulation Factor VII	Citrate Plasma	Coagulometry
Coagulation Factor VIII	Citrate Plasma	Coagulometry
Coagulation Factor VIII Inhibitor	Citrate Plasma	Coagulometry
Coagulation Factor IX	Citrate Plasma	Coagulometry
Coagulation Factor IX Inhibitor	Citrate Plasma	Coagulometry
Coagulation Factor X	Citrate Plasma	Coagulometry
Coagulation Factor XI	Citrate Plasma	Coagulometry
Coagulation Factor XII	Citrate Plasma	Coagulometry
Lupus-Anticoagulant	Citrate Plasma	Coagulometry
Protein-S activity	Citrate Plasma	Coagulometry
aPTT	Citrate Plasma	Coagulometry
PTZ	Citrate Plasma	Coagulometry
Thromboplastin Time (Quick)	Citrate Plasma	Coagulometry

Type of test:
Spectrometry (Fluorescence spectrometry)

Analyte (measurement parameter)	Test material (matrix)	Test technique
Thrombin generation test	Citrate Plasma	Fluorometry

Type of test:
Ligand assays*

Analyte (measurement parameter)	Test material (matrix)	Test technique
ACTH	EDTA-Plasma	Immunoassay (ECLIA)
ADMA	EDTA-Plasma	Immunoassay (EIA)
Adrenalin	EDTA-Plasma	Immunoassay (EIA)
AFP	Serum	Immunoassay (ECLIA)
alpha1-Antitrypsin	Stool	Immunoassay (EIA)
Anti-Müllerian-Hormone	Serum	Immunoassay (ECLIA)
Beta-Crosslaps (b-CTX)	Serum	Immunoassay (ECLIA)
Beta-HCG	Serum	Immunoassay (ECLIA)
BNP-pro-NT	Serum	Immunoassay (ECLIA)
Bone-AP	Serum	Immunoassay (EIA)

Analyte (measurement parameter)	Test material (matrix)	Test technique
CA-125	Serum	Immunoassay (ECLIA)
CA 19-9	Serum	Immunoassay (ECLIA)
Calcitonin	Serum	Immunoassay (ECLIA)
Calprotectin	EDTA-Plasma/Stool	Immunoassay (EIA)
CML/NE-(Carboxymethyl)-Lysin	Serum	Immunoassay (EIA)
Cortisol	Serum/Urine	Immunoassay (ECLIA)
C-Peptid	Serum	Immunoassay (ECLIA)
CTX II	Urine	Immunoassay (EIA)
D-Dimer	Citrate Plasma	Immunoassay (EIA)
DHEA	Serum	Immunoassay (EIA)
DHEA-SO4	Serum	Immunoassay (ECLIA)
Digoxin	Serum/Urine	Immunoassay (ECLIA)
Endothelin 1	Serum/Urine	Immunoassay (EIA)
Estradiol	Serum	Immunoassay (ECLIA)
Ferritin	Serum	Immunoassay (ECLIA)
FGF - 19	Serum	Immunoassay (EIA)
FGF - 21	Serum	Immunoassay (EIA)
FGF-23 C-terminal	Serum	Immunoassay (EIA)
FGF-23 intact	Serum	Immunoassay (EIA)
Folic acid	Serum	Immunoassay (ECLIA)
Folic acid (RBC)	Whole Blood	Immunoassay (ECLIA)
FSH	Serum	Immunoassay (ECLIA)
GHBP	Serum	Immunoassay (EIA)
GLP-1	Serum	Immunoassay (EIA)
Glucagon	P800 Plasma	Immunoassay (EIA)
Hepcidin	Serum	Immunoassay (EIA)
HER2/ErbB2	Serum	Immunoassay (EIA)
hGH	Serum	Immunoassay (CLIA)
hGH	Serum	Immunoassay (ECLIA)
IGF-1	Serum	Immunoassay (CLIA)
IGFBP-3	Serum	Immunoassay (CLIA)
Inhibin A	Serum	Immunoassay (EIA)
Inhibin B	Serum	Immunoassay (EIA)
Insulin	Serum	Immunoassay (ECLIA)
KIM-1	Urine	Immunoassay (EIA)
Leptin	Serum	Immunoassay (EIA)
LH	Serum	Immunoassay (ECLIA)
MCP-1	Serum	Immunoassay (EIA)
MPF	Serum	Immunoassay (EIA)
Myoglobin	Serum	Immunoassay (ECLIA)
NEFL (Neurofilament light)	Serum	Immunoassay (ECLIA)
Neopterin	Serum	Immunoassay (EIA)
Noradrenalin	EDTA-Plasma	Immunoassay (EIA)
NTx	Serum/Urine	Immunoassay (EIA)
Osteocalcin	Serum	Immunoassay (CLIA)
Osteocalcin	Serum	Immunoassay (ECLIA)
Osteoprotegrin	Serum	Immunoassay (EIA)
Oxytocin	EDTA-Plasma	Immunoassay (EIA)
P1NP	Serum	Immunoassay (ECLIA)
PAI-1 (activity)	Citrate Plasma	Immunoassay (EIA)

Analyte (measurement parameter)	Test material (matrix)	Test technique
PAI-1 (antigen)	Citrate Plasma	Immunoassay (EIA)
Progesterone	Serum	Immunoassay (ECLIA)
Proinsulin (intact)	Serum	Immunoassay (EIA)
Prolactin	Serum	Immunoassay (ECLIA)
Prothrombin fragment 1+2	Citrate Plasma	Immunoassay (EIA)
PSA (free)	Serum	Immunoassay (ECLIA)
PSA (total)	Serum	Immunoassay (ECLIA)
PTH intact	Serum	Immunoassay (ECLIA)
SHBG	Serum	Immunoassay (ECLIA)
SMRP	Serum	Immunoassay (CLEIA)
T3 free	Serum	Immunoassay (ECLIA)
T3 total	Serum	Immunoassay (ECLIA)
T4 free	Serum	Immunoassay (ECLIA)
T4 total	Serum	Immunoassay (ECLIA)
Testosterone	Serum	Immunoassay (ECLIA)
TFPI activity	Serum	Immunoassay (EIA)
TFPI free	Serum	Immunoassay (EIA)
TFPI total	Serum	Immunoassay (EIA)
Thrombin/Antithrombin III-Complex (TAT) Complex	Citrate Plasma	Immunoassay (EIA)
TRAP 5b	Serum	Immunoassay (EIA)
Troponin I	Serum	Immunoassay (CLEIA)
Troponin T	Serum	Immunoassay (ECLIA)
TSH	Serum	Immunoassay (ECLIA)
Vitamin B12	Serum	Immunoassay (ECLIA)
Vitamin-D 25-OH	Serum	Immunoassay (ECLIA)
vWF:Ag	Citrate Plasma	Immunoassay (EIA)
vWF:CBA	Citrate Plasma	Immunoassay (EIA)

Type of test:

Ligand assays**

Analyte (measurement parameter)	Test material (matrix)	Test technique
Anti-Tissue Transglutaminase AB	Serum	Immunoassay (EIA)
ZIK Screen	Serum	Immunoassay (EIA)

Type of test:

Microscopy*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Differential Blood Count	EDTA-Blood	Microscopy
Hemosiderin	Urine	Microscopy
Urine Sediment	Urine	Microscopy

Test area: Immunology

Type of test:

Microscopy *

Analyte (measurement parameter)	Test material (matrix)	Test technique
Anti-ds-DNA AB	Serum	Fluorescence Microscopy
Anti-Smooth-Muscle Cells AB	Serum	Fluorescence Microscopy
Antinuclear AB (ANA)	Serum	Fluorescence Microscopy
Liver-Kidney Microsomes I AB	Serum	Fluorescence Microscopy
Circulating tumor cells	EDTA-Blood	Fluorescence Microscopy

Type of test:

Flow cytometry **

Analyte (measurement parameter)	Test material (matrix)	Test technique
T- Lymphocyte subpopulations (CD3, CD4)	EDTA-Blood	Flow Cytometry
T- Lymphocyte subpopulations (CD3, CD4, CD8)	EDTA-Blood	Flow Cytometry
Lymphocyte differentiation (CD3, CD16/56, CD19, CD45)	EDTA-Blood	Flow Cytometry

Type of test:

Ligand assays**

Analyte (measurement parameter)	Test material (matrix)	Test technique
Anti-CCP	Serum	Immunoassay (ECLIA)
Anti-Thyroglobulin	Serum	Immunoassay (ECLIA)
Anti-TPO	Serum	Immunoassay (ECLIA)
C3a	Citrate Plasma	Immunoassay (EIA)
C4a	EDTA-Plasma	Immunoassay (EIA)
C5a	Citrate Plasma	Immunoassay (EIA)
CH 50	Serum	Immunoassay (EIA)
IgE	Serum	Immunoassay (ECLIA)
Interferon γ	Serum	Immunoassay (EIA)
Interferon γ	Serum	Immunoassay (ECLIA)
Interferon β	Serum	Immunoassay (ECLIA)
interleukin 1RA	Serum	Immunoassay (EIA)
Interleukin 6	Serum	Immunoassay (EIA)
Interleukin 6	Serum	Immunoassay (ECLIA)
Interleukin 8	Serum	Immunoassay (EIA)
Interleukin 8	Serum	Immunoassay (ECLIA)
Interleukin 17	Serum	Immunoassay (EIA)
Interleukin 17a	Serum	Immunoassay (ECLIA)
NEFL (Neurofilament light)	Serum	Immunoassay (ECLIA)
sICAM-1	Serum	Immunoassay (EIA)
TB-induced -IFN release (Quantiferon-TB Gold)	Plasma	Immunoassay (EIA)
TNF α	Serum	Immunoassay (ECLIA)

Type of test:

Spectrometry (nephelometry)*

Analyte (measurement parameter)	Test material (matrix)	Test technique
C3c complement	Serum	Immunonephelometry
C4 complement	Serum	Immunonephelometry
IgA	Serum	Immunonephelometry
IgG	Serum/Urine	Immunonephelometry
IgG1	Serum	Immunonephelometry
IgG2	Serum	Immunonephelometry
IgG3	Serum	Immunonephelometry
IgG4	Serum	Immunonephelometry
IgM	Serum/Urine	Immunonephelometry
Rheumatoid factor	Serum	Immunonephelometry

Type of test:

Spectrometry (UV/VIS photometry)*

Analyte (measurement parameter)	Test material (matrix)	Test technique
C1-Inhibitor	Citrate Plasma	Chromogenic Substrate

Test area: Microbiology

Type of test:

Ligand assays*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Haemophilus Influenza IgG	Serum	Immunoassay (EIA)
Tetanus IgG	Serum	Immunoassay (EIA)

Type of test:

Microscopy *

Analyte (measurement parameter)	Test material (matrix)	Test technique
Fungal Hyphae	KOH preparation	Microscopic
Dermatophytes	Culture / Lactophenolblue	Culture / Microscopic

Test area: Virology

Type of test:

Ligand assays*

Analyte (measurement parameter)	Test material (matrix)	Test technique
CMV IgG	Serum	Immunoassay (EIA)
HAV-AB	Serum	Immunoassay (ECLIA)
HAV-AB (IgM)	Serum	Immunoassay (ECLIA)
HB-c-AB	Serum	Immunoassay (ECLIA)
HB-c-AB (IgM)	Serum	Immunoassay (ECLIA)
HB-s-AG	Serum	Immunoassay (ECLIA)
HB-s-AB	Serum	Immunoassay (ECLIA)
HCV-AB	Serum	Immunoassay (ECLIA)
HIV-AG/AB	Serum	Immunoassay (ECLIA)
Measles IgG	Serum	Immunoassay (EIA)
SARS-CoV-2-AB	Serum	Immunoassay (ECLIA)
Anti-SARS-CoV-2-ELISA (IgA)	Serum	Immunoassay (EIA)
Anti-SARS-CoV-2-ELISA (IgG)	Serum	Immunoassay (EIA)

Type of test:

Molecular biological tests (amplification procedures)

Analyte (measurement parameter)	Test material (matrix)	Test technique
SARS-CoV-2	Oropharynx or combined nasooropharyngeal swab	Polymerase chain reaction (PCR)