Deutsche Akkreditierungsstelle

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

Valid from: **30.04.2026**

Date of issue: 30.04.2026

This annex is part of the Accreditation Certificate D-PL-13334-01-00.

Holder of the Accreditation Certificate:

GBA Central Lab Services GmbH
Lise-Meitner-Straße 25-29, 24223 Schwentinental

with the location

GBA Central Lab Services GmbH
Lise-Meitner-Straße 25-29, 24223 Schwentinental

The testing laboratory meets the requirements of DIN EN ISO/IEC 17025:2018 to carry out the conformity assessment activities listed in this annex. The testing laboratory meets additional legal and normative requirements, if applicable, including those in relevant sectoral schemes, provided that these are explicitly confirmed below.

The management system requirements of DIN EN ISO/IEC 17025 are written in the language relevant to the operations of testing laboratories and they conform to the principles of DIN EN ISO 9001.

Tests in the field of:

Medical Laboratory Testing within Clinical Trials

This annex to the certificate was issued by the Deutsche Akkreditierungsstelle GmbH (DAkkS) and is digitally sealed.
This annex to the certificate is only valid together with the written accreditation certificate and reflects the status as indicated by the date of issue. The current status of any valid and surveyed accreditation can be found in the directory of accredited bodies maintained by Deutsche Akkreditierungsstelle GmbH (www.dakks.de).

Abbreviations used: see last page

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Test areas:

Clinical Chemistry, Immunology, Microbiology and Virology

Flexible Scope of Accreditation:

Within the test areas indicated with * the testing laboratory is permitted without being required to prior inform and obtain approval from DAkkS, the free choice of standards or equivalent examination procedures.

Within the test areas indicated with ** the testing laboratory is permitted without being required to prior inform and obtain approval from DAkkS to modify, develop or further develop test methods.

The test methods listed are examples. The testing laboratory has an up-to-date list of all test methods within the flexible scope of accreditation. The list is publicly available on the website of the testing laboratory.

Medical Laboratory Testing within Clinical Trials

Clinical Chemistry

Flow cytometry (including particle characterisation)*

Analyte (measured parameter)	Test material (matrix)	Test method
Cellular blood count incl. differential	EDTA blood	Flow cytometry
Cellular blood count	EDTA blood	Flow cytometry
Differential blood count, automated	EDTA blood	Flow cytometry
NRBC (nucleated erythrocyte precursors)	EDTA blood	Flow cytometry
Reticulocytes	EDTA blood	Flow cytometry
Reticulocytes Haemoglobin	EDTA blood	Flow cytometry
Platelets	EDTA blood	Flow cytometry

Electrochemical analyses*

Analyte (measured parameter)	Test material (matrix)	Test method
Chloride	Serum/urine	Potentiometry (ISE)
Potassium	Serum/urine	Potentiometry (ISE)
Sodium	Serum/urine	Potentiometry (ISE)

Coagulometry*

Analyte (measured parameter)	Test material (matrix)	Test method
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

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Analyte (measured parameter)	Test material (matrix)	Test method
Coagulation factor X	Citrate plasma	Coagulometry
Lupus anticoagulant	Citrate plasma	Coagulometry
aPTT	Citrate plasma	Coagulometry
PTZ	Citrate plasma	Coagulometry
Thromboplastin time (Quick)	Citrate plasma	Coagulometry

Ligand assays*

Analyte (measured parameter)	Test material (matrix)	Test method
AFP	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)
Calcitonin	Serum	Immunoassay (ECLIA)
Calprotectin	Stool	Immunoassay (EIA)
Cortisol	Serum	Immunoassay (ECLIA)
D-Dimer	Citrate plasma	Immunoassay (EIA)
Estradiol	Serum	Immunoassay (ECLIA)
Ferritin	Serum	Immunoassay (ECLIA)
Folic acid	Serum	Immunoassay (ECLIA)
FSH	Serum	Immunoassay (ECLIA)
Glucagon	P800 Plasma	Immunoassay (EIA)
Hepcidin	Serum	Immunoassay (EIA)
hGH	Serum	Immunoassay (ECLIA)
IGF-1	Serum	Immunoassay (CLIA)
IGFBP-3	Serum	Immunoassay (CLIA)
Insulin	Serum	Immunoassay (ECLIA)
LH	Serum	Immunoassay (ECLIA)
P1NP	Serum	Immunoassay (ECLIA)
Progesterone	Serum	Immunoassay (ECLIA)
Prolactin	Serum	Immunoassay (ECLIA)
Prothrombin fragment 1+2	Citrate plasma	Immunoassay (EIA)
PSA (total)	Serum	Immunoassay (ECLIA)
T3 free	Serum	Immunoassay (ECLIA)
T3 total	Serum	Immunoassay (ECLIA)
T4 free	Serum	Immunoassay (ECLIA)
T4 total	Serum	Immunoassay (ECLIA)
Testosterone	Serum	Immunoassay (ECLIA)
Troponin T	Serum	Immunoassay (ECLIA)
TSH	Serum	Immunoassay (ECLIA)
Vitamin B12	Serum	Immunoassay (ECLIA)
Vitamin D 25-OH	Serum	Immunoassay (ECLIA)

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Microscopy*

Analyte (measured parameter)	Test material (matrix)	Testing method
Differential blood count, manual	EDTA blood	Microscopy
Urine sediment (including bacteria, epithelial cells and casts)	Urine	Microscopy

Spectrometry (fluorescence spectrometry)

Analyte (measured parameter)	Test material (matrix)	Test method
Thrombin generation test	Citrate plasma	Fluorometry

Spectrometry (immuno nephelometry)*

Analyte (measured parameter)	Test material (matrix)	Test method
Alpha-2-macroglobulin	Serum	Immunonephelometry
Cystatin C	Serum	Immunonephelometry
Haptoglobin	Serum	Immunonephelometry

Spectrometry (reflectometry/carrier-based assay)*

Analyte (measured parameter)	Test material (matrix)	Test method
Bilirubin	Urine	Reflectometry
Red blood cells/Erythrocytes	Urine	Reflectometry
Glucose	Urine	Reflectometry
Haemoglobin	Urine	Refractometry
Ketone	Urine	Reflectometry
Leukocytes	Urine	Refractometry
Nitrite	Urine	Refractometry
pH	Urine	Refractometry
Protein	Urine	Refractometry
Specific gravity	Urine	Refractometry
Urobilinogen	Urine	Refractometry

Spectrometry (turbidimetry/immunoturbidimetry)**

Analyte (measured parameter)	Test material (matrix)	Test method
Albumin	Urine	Immunoturbidimetry
Apolipoprotein B	Serum	Immunoturbidimetry
Calprotectin	Stool	Immunoturbidimetry
CRP	Serum	Immunoturbidimetry
Cystatin C	Serum	Immunoturbidimetry
Lipoprotein (a)	Serum	Immunoturbidimetry
HbA1c	Whole blood	Immunoturbidimetry
Prealbumin	Serum	Immunoturbidimetry
Protein	Urine	Turbidimetry
Transferrin	Serum	Turbidimetry

Spectrometry (UV/VIS photometry)*

Analyte (measured parameter)	Test material (matrix)	Testing method
Albumin	Serum/urine	Photometry
Alkaline phosphatase	Serum	Photometry

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Analyte (measured parameter)	Test material (matrix)	Testing method
Amylase	Serum	Photometry
Antithrombin III (activity)	Citrate plasma	Chromogenic colour test
Bicarbonate	Serum	Photometry
Direct bilirubin	Serum	Photometry
Total bilirubin	Serum	Photometry
Calcium	Serum/urine	Photometry
Cholesterol	Serum	Photometry
HDL cholesterol direct	Serum	Photometry
LDL cholesterol direct	Serum	Photometry
Cholinesterase	Serum	Photometry
CK NAC-activated	Serum	Photometry
CK-MB NAC-activated	Serum	Photometry
Creatinine (enzymatic)	Serum/urine	Photometry
Iron	Serum	Photometry
Free fatty acids	Serum	Photometry
Gamma-GT	Serum	Photometry
Coagulation factor VIII	Citrate plasma	Chromogenic colour test
Coagulation factor IX	Citrate plasma	Chromogenic colour test
GLDH	Serum	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
Magnesium	Serum/urine	Photometry
P-amylase	Serum	Photometry
Phosphate (inorganic)	Serum/urine	Photometry
Protein C (activity)	Citrate plasma	Chromogenic colour test
Total protein	Serum	Photometry
Triglycerides	Serum	Photometry

Immunology

Flow cytometry*

Analyte (measured parameter)	Test material (matrix)	Test method
Lymphocyte differentiation (CD3, CD4, CD8, CD16/56, CD19, CD45)	EDTA blood	Flow cytometry

Ligand assays**

Analyte (measured parameter)	Test material (matrix)	Test method
BB fragment	EDTA plasma	Immunoassay (EIA)
IgE	Serum	Immunoassay (ECLIA)
Interleukin 1-beta	Serum	Immunoassay (ECLIA)

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Analyte (measured parameter)	Test material (matrix)	Test method
Interleukin 6	Serum	Immunoassay (ECLIA)
Interleukin 8	Serum	Immunoassay (ECLIA)
Interleukin 10	Serum	Immunoassay (ECLIA)
TB-induced IFN release (Quantiferon-TB Gold)	Plasma (QFT-Plus collection tube)	Immunoassay (EIA)
TNF-α	Serum	Immunoassay (ECLIA)

Microscopy*

Analyte (measured parameter)	Test material (matrix)	Test method
Circulating tumour cells	EDTA blood	Fluorescence microscope

Spectrometry (immunonephelometry)*

Analyte (measured parameter)	Test material (matrix)	Test method
C3c complement	EDTA plasma	Immunonephelometry
IgA	Serum	Immunonephelometry
IgG	Serum	Immunonephelometry
IgM	Serum	Immunonephelometry

Microbiology

Ligand assays*

Analyte (measured parameter)	Test material (matrix)	Test method
Haemophilus influenzae IgG	Serum	Immunoassay (EIA)
Tetanus IgG	Serum	Immunoassay (EIA)

Virology

Ligand assays*

Analyte (measured parameter)	Test material (matrix)	Test method
CMV IgG	Serum	Immunoassay (EIA)
HAV-Ak	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)

Abbreviations used:

DIN	Deutsches Institut für Normung e.V. – German institute for standardization
EN	Europäische Norm – European Standard
IEC	International Electrotechnical Commission
ISO	International Organization for Standardisation

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