

# Deutsche Akkreditierungsstelle GmbH

## Annex to the Accreditation Certificate D-PL-14004-04-00 according to DIN EN ISO/IEC 17025:2018

**Valid from: 09.12.2019**

Date of issue: 09.12.2019

Holder of certificate:

**SYNLAB Analytics & Services Germany GmbH  
Turmstraße 21, Haus M Eingang O, 10559 Berlin**

Tests in the fields:

Healthcare (Medical Laboratory Testing within Clinical Trials)

**Testing area:**

Clinical chemistry

Immunology

Microbiology

Virology

Within the given testing field marked with \*), the testing laboratory is permitted, without being required to inform and obtain prior approval from DAkkS, the following: the free choice of standards or equivalent examination procedures. Within the given testing field 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 medical 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.**

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>*

**Test field: Clinical Chemistry**

**Test type:**

**Chromatography (High Pressure Liquid Chromatography (HPLC))\*\***

Analyte (measurement parameter)	Test Material (matrix)	Test Technology
HbA1c	EDTA Whole Blood	Ion Exchange -HPLC (High Pressure Liquid Chromatography)

**Test type:**

**Flowcytometry\*\***

Analyte (measurement parameter)	Test Material (matrix)	Test Technology
Leucocytes	EDTA Whole Blood	flow cytometric cell count measurement
Neutrophil Granulocytes	EDTA Whole Blood	flow cytometric cell count measurement
Eosinophil Granulocytes	EDTA Whole Blood	flow cytometric cell count measurement
Basophil Granulocytes	EDTA Whole Blood	flow cytometric cell count measurement
Monocytes	EDTA Whole Blood	flow cytometric cell count measurement
Erythrocytes	EDTA Whole Blood	flow cytometric cell count measurement
Reticulocytes	EDTA Whole Blood	flow cytometric cell count measurement
Thrombocytes	EDTA Whole Blood	flow cytometric cell count measurement
Haematocrit	EDTA Whole Blood	flow cytometric cell count measurement

**Test type:**

**Electrochemical tests\*\***

Analyte (measurement parameter)	Test Material (matrix)	Test Technology
Sodium	Serum, Urine	Potentiometry
Potassium	Serum, Urine	Potentiometry
Chloride	Serum, Urine	Potentiometry

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**Test type:**

**Electrophoresis\*\***

Analyte (measurement parameter)	Test Material (matrix)	Test Technology
Albumin	Serum	capillary electrophoresis
alpha-1-Globulin	Serum	capillary electrophoresis
alpha-2-Globulin	Serum	capillary electrophoresis
beta-1-Globulin	Serum	capillary electrophoresis
beta-2-Globulin	Serum	capillary electrophoresis
gamma-Globulin	Serum	capillary electrophoresis

**Test type:**

**Coagulometry\*\***

Analyte (measurement parameter)	Test Material (matrix)	Test Technology
Activated Partial Thromboplastin Time (aPTT)	Sodium Citrate Plasma	Coagulometry
Antithrombin III	Sodium Citrate Plasma	Coagulometry
Protein S	Sodium Citrate Plasma	Coagulometry
Protein C	Sodium Citrate Plasma	Coagulometry
D-Dimer	Sodium Citrate Plasma	Coagulometry
prothrombin time (Quick, PT)	Sodium Citrate Plasma	Coagulometry
Fibrinogen, Clauss	Sodium Citrate Plasma	Coagulometry
INR	Sodium Citrate Plasma	Calculated

**Test type:**

**Ligand binding assay\*\***

Analyte (measurement parameter)	Test Material (matrix)	Test Technology
ACTH	EDTA-Plasma	CLIA
Androstenedione	Serum	EIA
Aldosterone	Serum	EIA
beta-HCG	Serum	CMIA
Calcitonin	Serum	CLIA
Anti-CCP	Serum	CMIA
Cortisol	Serum	CMIA
C-Peptide	Serum	CMIA
DHEA	Serum	EIA
DHEAS	Serum	CMIA
Oestradiol	Serum	CMIA
Ferritin	Serum	CMIA
Free Thyroxine (fT4)	Serum	CMIA
Free Triiodothyronine (fT3)	Serum	CMIA
FSH	Serum	CMIA
Insulin	Serum	CMIA
LH	Serum	CMIA
BNP	Serum, EDTA Plasma	CMIA
NT-proBNP	Serum, EDTA Plasma	CLIA

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Analyte (measurement parameter)	Test Material (matrix)	Test Technology
Progesterone	Serum	CMIA
Prolactin	Serum	CMIA
PTH, intact	EDTA Plasma	CMIA
SHBG	Serum	CMIA
Testosterone, total	Serum	CMIA
Thyroid Stimulating Hormone (TSH)	Serum	CMIA
Thyroxine (T4)	Serum	CMIA
Triiodothyronine (T3)	Serum	CMIA
Troponin I	Serum	CLIA
Complement C3a	EDTA Plasma	EIA
Calprotectin	Stool	EIA
Complement C5a	EDTA Plasma	EIA
Alpha 1-Antitrypsin	Stool	EIA
Glucagon	Plasma	EIA

**Test type:**

**Microscopy\*\***

Analyte (measurement parameter)	Test Material (matrix)	Test Technology
Urine Sediment (bacteria, carbonate, epithelia, erythrocytes, granulated cylinders, hyaline cylinders, leucocytes, oxalates, mucus, triplet phosphate, urates)	Urine	Phase Contrast Microscopy
Manual RBC Morphology	Blood Film (EDTA Whole Blood)	Phase Contrast Microscopy
Manual Differential Cell Count	Blood Film (EDTA Whole Blood)	Phase Contrast Microscopy

**Test type:**

**Osmometry\*\***

Analyte (measurement parameter)	Test Material (matrix)	Test Technology
Osmolality	Serum, Urine	Cryoscopy

**Test type:**

**Qualitative analyses (simple) with visual evaluation**

Analyte (measurement parameter)	Test Material (matrix)	Test Technology
TCA (Tricyclic antidepressants)	Urine	Carrier-bound Immunoassay
MDMA (3,4-Methylenedioxy-N-methylamphetamine)	Urine	Carrier-bound Immunoassay

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**Test type:**

**Sedimentation analyses\*\***

Analyte (measurement parameter)	Test Material (matrix)	Test Technology
Erythrocyte Sedimentation Rate	Citrate Blood	Sedimentation

**Test type:**

**Spectrometry (nephelometry)\*\***

Analyte (measurement parameter)	Test Material (matrix)	Test Technology
Cystatin C	Serum, Urine, 24h Urine Collection	Nephelometry

**Test type:**

**Spectrometry (reflectometry/carrier-bound test procedures)\*\***

Analyte (measurement parameter)	Test Material (matrix)	Test Technology
Bilirubin	Urine	Reflectometry
Erythrocytes	Urine	Reflectometry
Glucose	Urine	Reflectometry
Ketone	Urine	Reflectometry
Leucocytes	Urine	Reflectometry
Nitrate	Urine	Reflectometry
Protein	Urine	Reflectometry
pH value	Urine	Reflectometry
Specific Gravity	Urine	Reflectometry
Urobilinogen	Urine	Reflectometry

**Test type:**

**Spectrometry (turbidimetry)\*\***

Analyte (measurement parameter)	Test Material (matrix)	Test Technology
Apolipoprotein B	Serum	Turbidimetry
Complement C4	Serum	Turbidimetry
Complement C3	Serum	Turbidimetry
CRP, hs	Serum	Turbidimetry
Haptoglobin	Serum	Turbidimetry
Transferrin	Serum	Turbidimetry

**Test type:**

**Spectrometry (UV-/VIS-photometry)\*\***

Analyte (measurement parameter)	Test Material (matrix)	Test Technology
ALAT/GPT	Serum	Photometry
ASAT/GOT	Serum	Photometry
Albumin	Serum	Photometry
Albumin	Urine	Photometry
Amphetamine	Urine	Photometry
Alkaline Phosphatase	Serum	Photometry

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<b>Analyte (measurement parameter)</b>	<b>Test Material (matrix)</b>	<b>Test Technology</b>
Alpha-1-Acidglycoprotein	Serum	Photometry
Amylase	Serum	Photometry
Bilirubin, total	Serum	Photometry
Bilirubin, direct	Serum	Photometry
Bilirubin, indirect	Serum	Calculated
Benzodiazepine	Urine	Photometry
Barbiturate	Urine	Photometry
Cannabinoid	Urine	Photometry
Cocaine	Urine	Photometry
Calcium	Serum, Urine	Photometry
Creatine kinase	Serum	Photometry
CK-MB	Serum	Photometry
Creatinine	Serum, Urine	Photometry
Cholesterol	Serum	Photometry
Cholinesterase	Serum	Photometry
Iron	Serum	Photometry
GLDH	Serum	Photometry
Glucose	Fluoride Plasma, Urine, Serum	Photometry
Gamma-GT	Serum	Photometry
Bile Acid	Serum	Photometry
Haemoglobin	EDTA Whole Blood	Photometry
HDL Cholesterol	Serum	Photometry
Uric Acid	Serum, Urine	Photometry
Urea	Serum, Urine	Photometry
Lactate	Fluoride Plasma	Photometry
LDH	Serum	Photometry
LDL Cholesterol	Serum	Photometry
Lipase	Serum	Photometry
Magnesium	Serum, Urine	Photometry
Methadone	Urine	Photometry
Opiate	Urine	Photometry
Amylase, Pancreatic	Serum	Photometry
Protein, total	Urine, Serum	Photometry
Phosphate, inorganic	Serum, Urine	Photometry
Bicarbonate	Serum	Photometry
Triglycerides	Serum	Photometry

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## Test field: Immunology

### Test type:

#### Flow cytometry\*

Analyte (measurement parameter)	Test Material (matrix)	Test Technology
Leucocytes CD45+	EDTA Whole Blood	immunophenotyping, haematology
T-Lymphocytes CD3+	EDTA Whole Blood	immunophenotyping, haematology
T-Lymphocytes CD4+	EDTA Whole Blood	immunophenotyping, haematology
T-Lymphocytes CD8+	EDTA Whole Blood	immunophenotyping, haematology
B-Lymphocytes CD19+	EDTA Whole Blood	immunophenotyping, haematology
HLA-DR+ Cells	EDTA Whole Blood	immunophenotyping, haematology
Natural Killer Cells (NK-Cells)	EDTA Whole Blood	immunophenotyping, haematology

### Test type:

#### Ligand binding assay\*

Analyte (measurement parameter)	Test Material (matrix)	Test Technology
IL-1beta	Serum	Multiplex-Assay
IL-6	Serum	Multiplex-Assay
IL-8	Serum	Multiplex-Assay
IL-10	Serum	Multiplex-Assay
IgE	Serum	CLIA
Interferon-Gamma (QuantiFERON-TB Gold)	Heparin Whole Blood	EIA
TNF-Alpha	Serum, Plasma	Multiplex-Assay
Microsomal Antibodies (MAK, Anti-TPO)	Serum	CLIA
Thyroglobulin Antibodies (TAK)	Serum	CLIA

### Test type:

#### Spectrometry (nephelometry)\*

Analyte (measurement parameter)	Test Material (matrix)	Test Technology
IgD	Serum	Nephelometry
Free Light Chains, Kappa	Serum	Nephelometry
Free Light Chains, Lambda	Serum	Nephelometry

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**Test type:**

**Spectrometry (turbidimetry)\***

Analyte (measurement parameter)	Test Material (matrix)	Test Technology
IgM	Serum	Turbidimetry
IgA	Serum	Turbidimetry
IgG	Serum	Turbidimetry
Rheumatoid Factor	Serum	Turbidimetry

**Test area: Microbiology**

**Test type:**

**Agglutination test**

Analyte (measurement parameter)	Test Material (matrix)	Test Technology
Treponema Pallidum Antibodies	Serum	Particle Agglutination Test

**Test field: Virology**

**Test type:**

**Ligand binding assay**

Analyte (measurement parameter)	Test Material (matrix)	Test Technology
HIV-AK combi+ p24 Ag	Serum	CMIA
HBs-Ag	Serum	CMIA
Anti-HBs	Serum	CMIA
Anti-HBc	Serum	CMIA
Anti-HBc IgM	Serum	CMIA
Anti-HAV	Serum	CMIA
Anti-HAV IgM	Serum	CMIA
Anti-HCV	Serum	CMIA

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