

# Deutsche Akkreditierungsstelle

## Annex to the Accreditation Certificate D-ML-13149-01-00 according to DIN EN ISO 15189:2014

**Valid from: 30.08.2023**

Date of issue: 30.08.2023

Holder of accreditation certificate

**SYNLAB Medizinisches Versorgungszentrum  
Labor München Zentrum GbR  
Schwanthalerstraße 115, 80339 München**

The medical laboratory meets the requirements of DIN EN ISO 15189:2014 to carry out the conformity assessment activities listed in this annex. The medical 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 15189 are written in the language relevant to the operations of medical laboratories and confirm generally with the principles of DIN EN ISO 9001.

### **Examinations in the field:**

Medical Laboratory Diagnostics

### **Medical laboratory fields:**

Clinical chemistry

Immunology

Human genetics (molecular human genetics)

Microbiology

Virology

Transfusion medicine

Within the given type of examination marked with \*), the medical 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 medical 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 certificate annex 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 given scope of accreditation can be found in the directory of accredited bodies maintained by Deutsche Akkreditierungsstelle GmbH at <https://www.dakks.de>.*

## Medical laboratory field: Clinical chemistry

### Type of examination:

#### Aggregometry

Analyte (measurement parameter)	Test material (matrix)	Test technique
Bleeding time	Citrate blood	Thrombocyte aggregation test

### Type of examination:

#### Chromatography (high performance liquid chromatography (HPLC)) \*\*

Analyte (measurement parameter)	Test material (matrix)	Test technique
5-Hydroxyindoleacetic acid	Urine	HPLC/ ECD
Aminod acids	Serum, EDTA-and Heparin-Plasma	HPLC/ FD
Amino acid profile	Serum, EDTA-Plasma, Urine	HPLC/MS-MS
CDT (Carbohydrate Deficient Transferrin)	Serum	HPLC/ UV/ VISD
Everolimus	EDTA-whole blood	LC/MS-MS
Glutathione (total)	EDTA-and Heparin-whole blood	HPLC/ FD
Glutathione (reduced)	EDTA-and Heparin-whole blood	HPLC/ FD
Heptacarboxyporphyrin	Urine	HPLC/ FD
Hexacarboxyporphyrin	Urine	HPLC/ FD
Hippuric acid	Urine	HPLC/ UV/ VISD
Koproporphyrin I	Urine	HPLC/ FD
Koproporphyrin III	Urine	HPLC/ FD
Metanephrin	Urine	HPLC/ ECD
Methylmaleic acid	Serum, Plasma, Urine	HPLC/MS-MS
Pentacarboxyporphyrin	Urine	HPLC/ FD
Quetiapin	Serum, Plasma	HPLC/MS-MS
Serotonin	Serum, Plasma, whole blood, Urine	HPLC/ ECD
Uroporphyrin	Urine	HPLC/ FD
Vitamin A (Retinol)	Serum, EDTA-Plasma	HPLC/ UV/ VISD
Vitamin B1	EDTA-and Heparin-whole blood	HPLC/ FD
Vitamin B6	EDTA-and Heparin-whole blood	HPLC/ FD
Vitamin C	Heparin - Plasma	HPLC/ UV/ VISD

**Type of examination:**

**Flow cytometry (including particle characteristic tests) \***

Analyte (measurement parameter)	Test material (matrix)	Test technique
Complete blood count	EDTA blood	Flow cytometry cell count and differentiation
Blood count	EDTA blood, Citrat blood	Flow cytometry cell count and differentiation
Platelets	Citrat blood	Flow cytometry cell count and differentiation
Cell count	Puncate	Flow cytometry cell count and differentiation

**Type of examination:**

**Electrochemical tests \***

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

**Type of examination:**

**Electrophoresis \***

Analyte (measurement parameter)	Test material (matrix)	Test technique
Albumin	Serum	Capillary electrophoresis
Alpha 1 antitrypsin-phenotype	Serum	Isoelectric focusing
Alpha-1-globulin	Serum	Capillary electrophoresis
Alpha-2-globulin	Serum	Capillary electrophoresis
Beta-globulin	Serum	Capillary electrophoresis
Gamma-globulin	Serum	Capillary electrophoresis
Hämoglobin-Varianten	EDTA-, Citrate- and Heparin-blood	Capillary electrophoresis
Lipids (HDL cholesterine)	Serum	Zone electrophoresis
Lipids (LDL cholesterine)	Serum	Zone electrophoresis
Proteinuria	Urine	Zone electrophoresis

**Type of examination:**

**Coagulometry \***

Analyte (measurement parameter)	Test material (matrix)	Test technique
Faktor VIII	Citrated plasma	Optical detection procedure
Fibrinogen	Citrated plasma	Optical detection procedure
Lupus anticoagulant	Citrated plasma	Optical detection procedure
Protein S functional	Citrated plasma	Optical detection procedure
Prothrombin time, Thromboplastin time (HepatoQuick)	Citrate blood	Mechanical detection procedure
Prothrombin time, Thromboplastin time (Quick, INR)	Citrated plasma	Optical detection procedure
PTT (activated partial thromboplastin time (aPTT))	Citrated plasma	Optical detection procedure

**Type of examination:**

**Ligand assays \*\***

Analyte (measurement parameter)	Test material (matrix)	Test technique
25 OH vitamin D	Serum, EDTA-and Lithium-Heparin-Plasma	Chemiluminescence immunoassay (CLIA)
Adrenocorticotrophic hormone (ACTH)	EDTA-Plasma	Chemiluminescence immunoassay (CLIA)
Aldosterone	Serum, Urine, EDTA-Plasma	Chemiluminescence immunoassay (CLIA)
Cannabinoids	Urine	Enzyme immunoassay (EIA)
Carbamazepin	Urine	Turbidimetric immuno assay (TIA)
Chromogranin A	Serum	Immunoradiometric assay (IRMA)
Cortisol	Serum, Saliva	Chemiluminescence immunoassay (CLIA), Enzyme immunoassay (EIA)
Folate	Serum, Erythrocytes	Chemiluminescence immunoassay (CLIA)
Metanephrin	EDTA-und Heparin-Plasma	Radioimmunoassay (RIA)
Neopterin	Serum, EDTA-Plasma	Enzyme immunoassay (EIA)
Neuron specific enolase (NSE)	Serum, cerebrospinal fluid	Chemiluminescence immunoassay (CLIA)
Oestradiol	Saliva	Enzyme immunoassay (EIA)
Oestradiol (E2)	Serum	Chemiluminescence immunoassay (CLIA)
Pancreatic elastase	Stool	Chemiluminescence immunoassay (CLIA)
Parathyroid hormone (PTH)	Serum, EDTA-Plasma	Chemiluminescence immunoassay (CLIA)
Progesteron	Saliva	Enzyme immunoassay (EIA)
PTH related Protein (PTHrP)	Plasma	Immunradiometrischer Assay (IRMA)

Analyte (measurement parameter)	Test material (matrix)	Test technique
Squamous Cell CA-antigen (SCC)	Serum, EDTA-Plasma, NH-Plasma	Chemiluminescence immunoassay (CLIA)
Testosterone (free)	Serum	Radioimmunoassay (RIA)

**Type of examination:**

**Microscopy \***

Analyte (measurement parameter)	Test material (matrix)	Test technique
Differential blood count	EDTA-whole blood, blood smear	Bright-field microscopy
Crystals	Synovial fluid	Polarisation microscopy
Urine sediment	Urine	Bright-field microscopy, Phase-contrast microscopy
Cell differentiation	Synovial fluid	Bright-field microscopy
Cell count	cerebrospinal fluid	Bright-field microscopy

**Type of examination:**

**Osmometry**

Analyte (measurement parameter)	Test material (matrix)	Test technique
Osmolality	Serum, Urine	Cryoscopy

**Type of examination:**

**Sedimentation tests**

Analyte (measurement parameter)	Test material (matrix)	Test technique
Erythrocyte sedimentation rate (ESR)	Citrate-, EDTA-whole blood	Sedimentation

**Type of examination:**

**Spectrometry (atom absorption spectroscopy (AAS)) \*\***

Analyte (measurement parameter)	Test material (matrix)	Test technique
Lead	EDTA-and Heparin-blood, Urine	Spectrometry (atomic absorption spectrometry (ASS))
Calcium	Urine	Spectrometry (atomic absorption spectrometry (ASS))
Chromium	Serum, Urine, EDTA-and Heparin-blood	Spectrometry (atomic absorption spectrometry (ASS))
Iron	EDTA-and Heparin-whole blood	Spectrometry (atomic absorption spectrometry (ASS))
Copper	Serum, Plasma	Spectrometry (atomic absorption spectrometry (ASS))
Magnesium	EDTA-and Heparin-whole blood	Spectrometry (atomic absorption spectrometry (ASS))
Selenium	Serum, Plasma, EDTA-and Heparin-blood	Spectrometry (atomic absorption spectrometry (ASS))
Zinc	Serum, Plasma, EDTA-and Heparin-whole blood, Urine	Spectrometry (atomic absorption spectrometry (ASS))

**Type of examination:**

**Spectrometry (Nephelometry) \***

Analyte (measurement parameter)	Test material (matrix)	Test technique
Alpha 1-Microglobulin	Urine	Nephelometry
Alpha 2-Macroglobulin	Urine	Nephelometry
Soluble transferrin receptor	Serum, Plasma	Nephelometry

**Type of examination:**

**Spectrometry (turbidimetry/Immunoturbidimetry) \***

Analyte (measurement parameter)	Test material (matrix)	Test technique
Albumin	Serum, cerebrospinal fluid	Turbidimetry
Albumin (Microalbumin)	Urine	Turbidimetry
Beta-2-Microglobulin	Serum, Urine	Turbidimetry
C-reaktive protein (CRP)	Serum	Immunoturbidimetry
Fibrin degradation products D-Dimer	Citrated plasma	Immunoturbidimetry
Hemoglobin fecal	Stool	Turbidimetry
vWFAC (vW-Factor-Activity)	Citrated plasma	Immunoturbidimetry

**Type of examination:**

**Spectrometry (IR-spectrometry)**

Analyte (measurement parameter)	Test material (matrix)	Test technique
Helicobacter pylori (13CO2)	respiratory sample	IR-Spectrometry
Stone analysis	Bladder stone, Gall stone and Urinary stone	IR-Spectrometry

**Type of examination:**

**Spectrometry (mass spectrometry (MS/MS-MS)) \*\***

Analyte (measurement parameter)	Test material (matrix)	Test technique
Iodine	Serum, Plasma, Urine	Mass spectrometry (MS/MS-MS)
Copper	EDTA blood, Urine	Mass spectrometry (MS/MS-MS)
Molybdenum	Serum, EDTA-and Heparin -Plasma, Urine, EDTA-and Heparin- blood	Mass spectrometry (MS/MS-MS)
Mercury	EDTA- and Heparin-blood, Urine	Mass spectrometry (MS/MS-MS)

**Type of examination:**

**Spectrometry (reflectometry / solid phase tests)**

Analyte (measurement parameter)	Test material (matrix)	Test technique
Urinalysis	Urine	Reflectometry

**Type of examination:**

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

Analyte (measurement parameter)	Test material (matrix)	Test technique
Alanine-Aminotransferase (ALT) or Glutamate-Pyruvate-Transaminase (GPT)	Serum	VIS-photometry
Aldolase	Serum, EDTA-and Heparin-Plasma	UV-/ VIS-photometry
Angiotensin-Converting Enzyme (ACE)	Serum, broncho-alveolar lavage	UV-/ VIS-photometry
Anti factor 10 a - activity	Citrated plasma	UV-/ VIS-photometry
Aspartat-Aminotransferase (AST) or Glutamate-Oxalacetate-Transaminase (GOT)	Serum	VIS-photometry
Fructose	Ejaculate	UV-/ VIS-photometry
Gallenic acid	Serum, EDTA-Plasma	UV-/ VIS-photometry
Gamma-Glutamyl-Tranferase (GGT)	Serum	VIS-photometry
Glucose	Sodium-Fluoride-Citrat Plasma, Sodium-Fluoride- Plasma, cerebrospinal fluid, Urine	VIS-photometry
Urea	Serum, Urine	VIS-photometry
Catalase activity in erythrocytes	EDTA-and Sodium-Natrium-Heparin-whole blood	UV-/ VIS-photometry
Kryptopyrrol (Mauve-Factor)	Urine	UV-/ VIS-photometry
Lactate	Sodium-Fluoride-Plasma	VIS-photometry
Porphobilinogen	Urine	UV-/ VIS-photometry
Protein C functional	Citrated plasma	UV-/ VIS-photometry
Superoxide dismutase	EDTA-and Sodium-Heparin- blood	UV-/ VIS-photometry

**Medical laboratory field: Immunology**

**Type of examination:**

**Flow cytometry (including particle characterstic tests) \*\***

Analyte (measurement parameter)	Test material (matrix)	Test technique
Basophil activation test (BAT)	EDTA-whole blood	Flow cytometry cell count and differentiation
B- cell-typing	Sodium heparin blood, EDTA blood, bone marrow	Flow cytometry cell differentiation
CD34 stem cells	Heparin-blood	Immunophenotyping immunology
CD4:g-INF basal	Heparin-blood	Immunophenotyping immunology

Analyte (measurement parameter)	Test material (matrix)	Test technique
CD4:g-INF stimulated	Heparin-blood	Immunophenotyping immunology
CD4:IL4 basal	Heparin-blood	Immunophenotyping immunology
CD4:IL4 stimulatd	Heparin-blood	Immunophenotyping immunology
Cytokine check IL-2, IL-4, IL-5, IL-6, IL-7, IL-8, IL-9, IL-10, IL-12. IL-13,IL-15, IL-17A, IL-18, IL-21, IL-22, IL-23, IL-27, IL-31, TNF-alpha, TNF-beta, IFN-alpha, IFN-gamma, IL-1 alpha, IL-1 beta, IL-1 Rezeptor Antagonist, MIP-1 alpha, MIP-1 beta, CCL2 (MCP1), CCL5 (RANTES), CXCL1 (GRO alpha), CXCL12 alpha (SDF-1 alpha), CXCL10 (IP-10), Eotaxin, GM-CSF	Serum, Plasma	Flow cytometry using colour-coded beads (particle-based multiplex assays)
HLA B27	CPDA-blood, EDTA-and Heparin-blood, Citrate- blood	Immunophenotyping immunology
Lymphocyte differentiation	Bronchial lavage	Flow cytometry cell differentiation
Lymphocyte typing / lymphocyte sub-populations	EDTA blood, Heparin blood, CPDA-blood, Citrate Blood	Flow cytometry cell differentiation
NK cells (function test)	Sodium heparin blood	Cell and funktion analyses with fluorescent dyes incl. cell proliferation measurement and cell cycle analysis
NK-modulators CD69/16	Sodium heparin blood	Cell and funktion analyses with fluorescent dyes incl. cell proliferation measurement and cell cycle analysis

**Type of examination:**

**Electrophoresis \***

Analyte (measurement parameter)	Test material (matrix)	Test technique
free light chains (Bence Jones protein)	Serum, Urine	Immunofixation electrophoresis
Isoenzym of the alkaline phosphatase	Serum	Zone electrophoresis
IgG-specific oligoclonal bands	cerebrospinal fluid, Serum	Isoelectric focusing



**Type of examination:**

**Ligand assays \*\***

Analyte (measurement parameter)	Test material (matrix)	Test technique
Autoantibodies against acetylcholine receptor	Serum, EDTA-Plasma	Receptor assay
Autoantibodies against Insulin (ISAG)	Serum	Radioimmunoassay (RIA)
Anti citrullinated peptide (CCP)	Serum	fluorescence immuno assay (FIA)
Eosinophil cationic protein (ECP)	Serum, Nasal secretion	fluorescence immuno assay (FIA)
Diaminooxidase	Serum	Enzyme immunoassay (EIA)
Neurological diseases: autoantibodies against Amphiphysin, CV2, HU, PNMA2 (Ma2/Ta), RI, YO	Serum, Plasma, cerebrospinal fluid	Immunoblot (Westernblot)
Histamine	Stool	Enzyme immunoassay (EIA)
Histamine free	Heparin-Plasma, EDTA-Plasma, Urine	Enzyme immunoassay (EIA)
Histamine total	Sodium heparin blood	Enzyme immunoassay (EIA)
IgE (total)	Serum, whole blood	fluorescence immuno assay (FIA)
Interleukin 1 beta	Heparin-Plasma, Serum	Chemiluminescence immunoassay (CLIA)
Interleukin 2 receptor	EDTA-Plasma, Serum	Chemiluminescence immunoassay (CLIA)
Interleukin 6	Serum, EDTA- und Heparin-Plasma	Chemiluminescence immunoassay (CLIA)
organ-specific autoimmune diseases: Autoantibodies against AMA M2	Serum, EDTA-, Heparin-and Citrated-Plasma	Enzyme immunoassay (EIA)
organ-specific autoimmune diseases: Autoantibodies against AMA M2, LC-1, LKM-1, M2-3E (BPO), SLA/LP	Serum, EDTA-, Heparin-and Citrated-Plasma	Immunoblot (Westernblot)
organ-specific autoimmune diseases: Autoantibodies against AMA M2, SLA, LC-1, gp210, LKM-1, M2-3E (BPO), PML, SP 100	Serum, EDTA-, Heparin-and Citrated-Plasma	Immunoblot (Westernblot)
organ-specific autoimmune diseases: Autoantibodies against BP180, BP230, Desmoglein 1, Desmoglein 3, Envoplakin, collagen type VII	Serum, EDTA-, Heparin-and Citrated-Plasma	Enzyme immunoassay (EIA)

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Analyte (measurement parameter)	Test material (matrix)	Test technique
organ-specific autoimmune diseases: Autoantibodies against GAD	Serum, EDTA-Plasma	Enzyme immunoassay (EIA)
organ-specific autoimmune diseases: Autoantibodies against Gliadin	Serum, EDTA-, Heparin-and Citrated-Plasma	Enzyme immunoassay (EIA)
organ-specific autoimmune diseases: Autoantibodies against IA2	Serum, EDTA-, Heparin-and Citrated-Plasma	Enzyme immunoassay (EIA)
organ-specific autoimmune diseases: Autoantibodies against intrinsic factor	Serum, EDTA-, Heparin-and Citrated-Plasma	Enzyme immunoassay (EIA)
organ-specific autoimmune diseases: Autoantibodies against parietal cells	Serum, EDTA-, Heparin-and Citrated-Plasma	Enzyme immunoassay (EIA)
organ-specific autoimmune diseases: Autoantibodies against Saccharomyces cerevisiae	Serum, EDTA-, Heparin-and Citrated-Plasma	Enzyme immunoassay (EIA)
organ-specific autoimmune diseases: Autoantibodies against SLA	Serum, EDTA-, Heparin-and Citrated-Plasma	Enzyme immunoassay (EIA)
organ-specific autoimmune diseases: Autoantibodies against tTG IgA	Serum, EDTA-, Heparin-and Citrated-Plasma	Enzyme immunoassay (EIA)
PSA, high sensitive	Serum	Chemiluminescence immunoassay (CLIA)
secretory IgA	Stool, Sputum	Enzyme immunoassay (EIA) fluorescence immuno assay (FIA)
specific IgE	Serum	fluorescence immuno assay (FIA)
specific IgG	Serum	fluorescence immuno assay (FIA)
specific IgG4	Serum	fluorescence immuno assay (FIA)
Systemic autoimmune diseases: autoantibodies against EJ, Mi-2, OJ, Jo-1, PL 12, PL-7, PM-SCL 100, PM-SCL 75, SRP, KU	Serum, EDTA-, Heparin-and Citrated-Plasma	Immunoblot (Westernblot)
Systemic autoimmune diseases: autoantibodies against ANCA-Profile	Serum, EDTA-, Heparin-and Citrated-Plasma	Enzyme immunoassay (EIA)

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Analyte (measurement parameter)	Test material (matrix)	Test technique
Systemic autoimmune diseases: autoantibodies against ds-DNS	Serum, EDTA-, Heparin-and Citrated-Plasma	Enzyme immunoassay (EIA)
Systemic autoimmune diseases: autoantibodies against ds-DNS, Histones, Nucleosome, Ro-52, Jo-1, PM-SCL, SCL-70, CENP B, PCNA, nRNP/Sm, ribosomale P-Protein, Sm, SSA, SSB, DSF 70	Serum, EDTA-, Heparin-and Citrated-Plasma	Immunoblot (Westernblot)
Systemic autoimmune diseases: autoantibodies against ENA-Pool (nRNP/ SM, SM, SSA, SSB, SCL 70, Jo1)	Serum, EDTA-, Heparin-and Citrated-Plasma	Enzyme immunoassay (EIA)
Systemic autoimmune diseases: autoantibodies against GBM	Serum, EDTA-, Heparin-and Citrated-Plasma	Enzyme immunoassay (EIA)
Systemic autoimmune diseases: autoantibodies against JO1	Serum, EDTA-, Heparin-and Citrated-Plasma	Enzyme immunoassay (EIA)
MPO, Proteinase 3	Serum, EDTA-, Heparin-and Citrated-Plasma	Enzyme immunoassay (EIA)
Systemic autoimmune diseases: autoantibodies against nRNP/SM	Serum, EDTA-, Heparin-and Citrated-Plasma	Enzyme immunoassay (EIA)
Systemic autoimmune diseases: autoantibodies against PM-SCL 100, PM-SCL 75, SCL-70, RO52, CENP A, CENP B, PDGFR, Ku, NOR 90, Fibrillarin (U3-RNP), RP 11, RP 155, Th/To	Serum, EDTA-, Heparin-and Citrated-Plasma	Immunoblot (Westernblot)
Systemic autoimmune diseases: autoantibodies against SCL70	Serum, EDTA-, Heparin-and Citrated-Plasma	Enzyme immunoassay (EIA)
Systemic autoimmune diseases: autoantibodies against SM	Serum, EDTA-, Heparin-and Citrated-Plasma	Enzyme immunoassay (EIA)
Systemic autoimmune diseases: autoantibodies against SSA (Ro) 60 kDa	Serum, EDTA-, Heparin-and Citrated-Plasma	Enzyme immunoassay (EIA)

Analyte (measurement parameter)	Test material (matrix)	Test technique
Systemic autoimmune diseases: autoantibodies against SSB (LA)	Serum, EDTA-, Heparin-and Citrated-Plasma	Enzyme immunoassay (EIA)
Tumour necrosis factor alpha	Heparin Plasma, Serum	Chemiluminescence immunoassay (CLIA)

**Type of examination:**

**Microscopy \***

Analyte (measurement parameter)	Test material (matrix)	Test technique
Autoantibodies against anti-nuclear antigene (ANA)	Serum, EDTA-, Heparin-and Citrated-Plasma	Fluorescence microscopy
Neurological diseases: autoantibodies against diagonal fibre muscle (cardiac muscle and sceletal muscle)	Serum, EDTA-, Heparin-and Citrated-Plasma	Fluorescence microscopy
organ-specific autoimmune diseases: Autoantibodies against endomysium	Serum, EDTA-, Heparin-and Citrated-Plasma	Fluorescence microscopy
organ-specific autoimmune diseases: Autoantibodies against epidermal basal lamina, acanthocyte desmosomes	Serum, EDTA-, Heparin-and Citrated-Plasma	Fluorescence microscopy
organ-specific autoimmune diseases: Autoantibodies against F-Aktin, ASMA, LKM 1, AMA, Elastin	Serum, EDTA-, Heparin-and Citrated-Plasma	Fluorescence microscopy
organ-specific autoimmune diseases: Autoantibodies against islet cell	Serum, EDTA-, Heparin-and Citrated-Plasma	Fluorescence microscopy
organ-specific autoimmune diseases: Autoantibodies against LKM, AMA	Serum, EDTA-, Heparin-and Citrated-Plasma	Fluorescence microscopy
Vasculitis: autoantibodies against GBM, TUBK	Serum, EDTA-, Heparin-and Citrated-Plasma	Fluorescence microscopy
Vasculitis: autoantibodies against p-ANCA, c-ANCA, xANCA	Serum, EDTA-, Heparin-and Citrated-Plasma	Fluorescence microscopy

**Type of examination:**

**Spectrometry (Turbidimetry/Immunoturbidimetry)\***

Analyte (measurement parameter)	Test material (matrix)	Test technique
Free light chains (Kappa and Lambda)	Urine, Serum	Turbidimetry
total complement (CH50)	Serum	Turbidimetry
Immunglobulin A	Serum, cerebrospinal fluid	Turbidimetry, Immunoturbidimetry
Immunglobulin G	Serum, cerebrospinal fluid	Turbidimetry, Immunoturbidimetry
Immunglobulin G subclass 1	Serum	Turbidimetry
Immunglobulin G subclass 2	Serum	Turbidimetry
Immunglobulin G subclass 3	Serum	Turbidimetry
Immunglobulin G subclass 4	Serum	Turbidimetry
Immunglobulin M	Serum, cerebrospinal fluid	Turbidimetry, Immunoturbidimetry
Rheumatoid factor (RF)	Serum	Immunoturbidimetry

**Type of examination:**

**Functional cell assays \*\***

Analyte (measurement parameter)	Test material (matrix)	Test technique
Phagocytosis	Sodium heparin blood	Determination of oxidative burst
T-cell proliferation	Sodium heparin blood	Lymphocyte transformation test
Release of IFN- $\gamma$ after stimulation with M-tuberculosis antigen	whole blood, Sodium Heparin Blood, Citrate Blood	Zytokinrelease, measurement of Zytokine with Enzyme immunoassay (EIA), fluorescence immuno assay (FIA)

**Medical laboratory field: Human Genetics (Molecular Human Genetics)**

**Type of examination:**

**Molecular biological tests (amplification procedures) \***

Analyte (measurement parameter)	Test material (matrix)	Test technique
Faktor II gene, mutation 20210 G>A	EDTA blood	Real-time PCR
Faktor V gene, mutation 1691 G>A	EDTA blood	Real-time PCR
Hereditary fructose intolerance, mutations A149P, A174D, N334K and D4E4	EDTA-Blut	PCR, line Probe Assay
HFE gene (hereditary haemochromatosis) mutation C282Y, H63D)	EDTA blood	Real-time PCR
HLA B27	EDTA blood	Real-time PCR

## Medical laboratory field: Microbiology

### Type of examination:

#### Agglutination tests \*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Echinococcus (antibodies)	Serum	Haemagglutination test
Salmonella (antigen)	Bacteria culture	Particle agglutination test
Shigella (antigen)	Bacteria culture	Particle agglutination test
Staphylococcus aureus (Gram positive aerobic and facultative anaerobic cocci)	Bacteria culture	Particle agglutination test
Streptococcaceae (Gram positive aerobic and facultative anaerobic cocci)	Bacteria culture	Particle agglutination test
Streptococci (anti-DNase B) (antibodies)	Serum	Particle agglutination test
Streptococci (hyaluronidase) (antibodies)	Serum	Particle agglutination test
Treponema pallidum (antibodies)	Serum, Plasma, cerebrospinal fluid	Particle agglutination test
Treponema pallidum (Cardiolipin)	Serum, Plasma	Particle agglutination test
Yersinia (antigen)	Bacteria culture	Particle agglutination test

### Type of examination:

#### Sensitivity testing of bacteria and fungi \*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Aerobe bacteria	Bacteria culture	Agar diffusion test, Bouillon dilution procedure as minimum inhibitory concentration (MIC)/break-point
Anaerobe bacteria	Bacteria culture	Agar dilution test, Bouillon dilution procedure as minimum inhibitory concentration (MIC)/break-point
Gram negative aerobic and facultative anaerobic rods (Enterobacter, vibrions, aeromonas, sophisticated gram neg. rods), Darm-pathogene E.coli, Shigella, Salmonella, Yersinia, Pasteurella, Haemophilus, Non-fermenter, Acinetobacter, Legionella)	Bacteria culture, Urine	Agar diffusion test, Bouillon dilution procedure as minimum inhibitory concentration (MIC)/break-point

Analyte (measurement parameter)	Test material (matrix)	Test technique
Yeasts	Fungal culture	Bouillon dilution procedure as minimum inhibitory concentration (MIC)/break-point
Helicobacter spp. (gram negative rods)	Bacteria culture	Bouillon dilution procedure as minimum inhibitory concentration (MIC)/break-point
Multi-resistant gram negative bacteria (MRGN)	Bacteria culture	Bouillon dilution procedure as minimum inhibitory concentration (MIC)/break-point
Multi-resistant Staphylococcus aureus (MRSA)	Bacteria culture	Bouillon dilution procedure as minimum inhibitory concentration (MIC)/break-point
Mycoplasma spp.	Urine, genital swab, vaginal swab, urethral swab	Bouillon dilution procedure as minimum inhibitory concentration (MIC)/break-point
Ureaplasma spp.	Urine, genital swab, vaginal swab, urethral swab	Bouillon dilution procedure as minimum inhibitory concentration (MIC)/break-point

**Type of examination:**

**Germ differentiation/identification/typing \***

Analyte (measurement parameter)	Test material (matrix)	Test technique
Aerobe bacteria	Bacteria culture	biochemical, Matrix assisted laser desorption ionisation-time of flight / mass spectrometry
Anaerobe bacteria	Bacteria culture	biochemical, Matrix assisted laser desorption ionisation-time of flight / mass spectrometry
Gram negative aerobic and facultative anaerobic rods (Enterobacter, vibrions, aeromonas, sophisticated gram neg. rods), Darm-pathogene E.coli, Shigella, Salmonella, Yersinia, Pasteurella, Haemophilus, Non-fermenter, Acinetobacter, Legionella)	Bacteria culture	biochemical, Matrix assisted laser desorption ionisation-time of flight / mass spectrometry
Gram negative aerobic and facultative anaerobic cocci (Neisseria, Moraxella)	Bacteria culture	biochemical

Analyte (measurement parameter)	Test material (matrix)	Test technique
Gram negative anaerobic cocci (Veillonella)	Bacteria culture	biochemical
Gram negative glucose fermenting rods	Bacteria culture	Matrix assisted laser desorption ionisation-time of flight / mass spectrometry
Gram positive aerobic and facultative anaerobic cocci (Streptococcaceae, Staphylococcaceae, Micrococcaceae, Dermacoccaceae)	Bacteria culture	biochemical, Matrix assisted laser desorption ionisation-time of flight / mass spectrometry
Gram positive aerobic and facultative anaerobic rods (coryneform rods, Gardnerella vaginalis, Listeria spp., Erysipelothrix rhusiopathiae, aerobic Actinomycetaceae, Bacillus spp.)	Bacteria culture	biochemical
Yeasts (Candida spp.), hyalohyphomycetes (Aspergillus spp.), dermatophytes (Trichophyton spp.)	Fungal culture	biochemical, Matrix assisted laser desorption ionisation-time of flight / mass spectrometry
Helicobacter spp. (Gram negative rods)	Bacteria culture	biochemical
Mycoplasma spp.	Urine, genital swab, vaginal swab, urethral swab	biochemical
Ureaplasma spp.	Urine, genital swab, vaginal swab, urethral swab	biochemical

**Type of examination:**

**Culture tests \***

Analyte (measurement parameter)	Test material (matrix)	Test technique
Aerobe and anaerobe bacteria	Varia material, Biopsies, Urine, Stool, blood culture, orthopaedic samples, catheter tips, Sputum, BAL, nasal swab, throat swab, cerebrospinal fluid, punctate, cerebrospinal fluid	Enrichment process, in anaerobic atmosphere, in a microaerobic atmosphere, specific (selective), non-specific (non-selective), germ count determination
Yeasts (Candida spp.), hyalohyphomycetes (Aspergillus spp.)	Varia material, biopsies, Urine, Stool, blood culture, orthopaedic samples, catheter tips, Sputum, BAL, nasal swab, throat swab, punctate, cerebrospinal fluid	Enrichment process; in a microaerobic atmosphere, specific (selective),



Analyte (measurement parameter)	Test material (matrix)	Test technique
Helicobacter spp. (gram negative rods)	stomach biopsy	in CO <sub>2</sub> -enriched atmosphere, specific (selective), non-specific (non-selective)
Mycoplasma spp.	Urine, Genital smear, vaginal Swab, urethral swab	in anaerobic atmosphere, in a microaerobic atmosphere, specific (selective), germ count determination
Ureaplasma spp.	Urine, Genital smear, vaginal Swab, urethral swab	in anaerobic atmosphere, in a microaerobic atmosphere, specific (selective), germ count determination

### Type of examination:

#### Ligand assays \*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Bordetella pertussis (IgG-, IgA-antibodies)	Serum	Chemiluminescence immunoassay (CLIA)
Borrelia (IgG-, IgM-antibodies, spez. AI)	Serum, cerebrospinal fluid	Enzyme immunoassay (EIA), Chemiluminescence immunoassay (CLIA), Immunoblot (Westernblot)
Chlamydia trachomatis (IgG-, IgA-antibodies)	Serum	Enzyme immunoassay (EIA)
Chlamydia pneumoniae (IgG-, IgA-, IgM-antibodies)	Serum	Enzyme immunoassay (EIA)
Clostridioides difficile (Toxin A)	Stool	Enzyme immunoassay (EIA)
Clostridioides difficile Antigen	Stool	Enzyme immunoassay (EIA)
Clostridioides difficile Toxin (A+B)	Stool	Enzyme immunoassay (EIA)
Entamoeba histolytica (antigen)	Stool	Enzyme immunoassay (EIA)
Gardia lamblia (antigen)	Stool	Enzyme immunoassay (EIA)
Helicobacter pylori (antigen)	Stool	Enzyme immunoassay (EIA)
Helicobacter pylori (IgG-, IgA-antibodies)	Serum, Plasma	Immunoblot (Westernblot)
Legionella	Urine	Enzyme immunoassay (EIA)
Methicillin-resistant Staphylococcus aureus (MRSA)	Bacteria culture	Enzyme immunoassay (EIA)
Mycoplasma pneumoniae (IgG-, IgA-, IgM-antibodies)	Serum	Enzyme immunoassay (EIA)
Plasmodium spp. (IgG-antibodies)	Serum	Enzyme immunoassay (EIA)
Toxoplasma gondii (IgG-antibodies, IgM-antibodies)	Serum, Plasma	Chemiluminescence immunoassay (CLIA)
Toxoplasmosis (IgG and IgA-antibodies, IgG-avidity)	Serum, Plasma	Enzyme immunoassay (EIA)
Treponema pallidum (IgG, IgM-antibodies)	Serum, Plasma	Chemiluminescence immunoassay (CLIA), Immunoblot (Westernblot)

**Type of examination:**

**Microscopy \***

Analyte (measurement parameter)	Test material (matrix)	Test technique
Aerobe and anaerobe bacteria	Varia material, Biopsies, Urine, blood culture, orthopaedic samples, Bacteria culture, punctate, cerebrospinal fluid, BAL	Bright-field microscopy
Bartonella haensele (IgG-, IgM-antibodies)	Serum	Fluorescence microscopy
Bartonella quintana (IgG-, IgM-antibodies)	Serum	Fluorescence microscopy
Gram positive aerobic and facultative anaerobic rods (coryneform rods, Gardnerella vaginalis, Listeria spp., Erysipelothrix rhusiopathiae, aerobic actinomycetaceae, Bacillus spp.)	Bacteria culture	Bright-field microscopy
Yeasts (e.g. Candida spp.), hyalohyphomycetes (Aspergillus spp.), dermatophytes (Trichophyton spp.)	Fungal culture	Bright-field microscopy
Parasites of the urogenital tract (Trichomonas)	Urine	Bright-field microscopy
Parasites of the intestine and of organs attached to the intestine (intestinal parasites, amoebae, sporozoa, coccidia, ciliates, trematodes, cestodes, nematodes)	Stool, Urine, duodenal juice, protozoa	Bright-field microscopy
Plasmodium spp.	EDTA-whole blood, swab	Bright-field microscopy
Treponema vincentii and Fusobacterium nucleatum	throat swab	Bright-field microscopy

**Type of examination:**

**Molecular biological tests (amplification procedures) \***

Analyte (measurement parameter)	Test material (matrix)	Test technique
Bordetella pertussis	Nasopharyngeal swab, BAL, Sputum	Real-time PCR (fluorescence-labeled hybridization probes)
Borrelia burgdorferi sensu lato	Urine, cerebrospinal fluid, joint puncture, skin punches	Real-time PCR (fluorescence-labeled hybridization probes)

Analyte (measurement parameter)	Test material (matrix)	Test technique
Chlamydia pneumoniae	Sputum, BAL, nasal swab, throat swab	Real-time PCR (fluorescence-labeled hybridization probes)
Chlamydia trachomatis	Swab, Urine	Real-time PCR (fluorescence-labeled hybridization probes)
Dermatophytes (C. albicans, Trichophyton spec., Microsporum spec., E. floccosum)	Nail-, skin-, hair-sample culture	Real-time PCR (fluorescence-labeled hybridization probes) with melting point analysis of the amplification products
enterohaemorrhagic Escherichia coli (EHEC)	Bacteria culture, stool enrichment	Real-time PCR (fluorescence-labeled hybridization probes)
Legionella pneumophila	BAL, Sputum, tracheal secretion	Real-time PCR (fluorescence-labeled hybridization probes)
Methicillin resistant staphylococcus	Swab, culture, cerebrospinal fluid	Real-time PCR (fluorescence-labeled hybridization probes)
Mycoplasma pneumoniae	Sputum, BAL, nasal swab, throat swab	Real-time PCR (fluorescence-labeled hybridization probes)
Mycoplasma screening (Mycoplasma hominis, M. genitalium, Ureaplasma urealyticum/parvum)	Urine, vaginal Swab, Cervical smear, anal swab, urethral swab, eye swab	Real-time PCR (fluorescence-labeled hybridization probes)
Neisseria gonorrhoeae	Swab, Urine	Real-time PCR (fluorescence-labeled hybridization probes)
Sexually transmitted diseases (STD-Screening: Chlamydia trachomatis, Neisseria gonorrhoeae, Trichomonas vaginalis, Treponema pallidum)	Urine, vaginal Swab, Cervical smear, anal swab, urethral swab, eye swab	Real-time PCR (fluorescence-labeled hybridization probes)

**Type of examination:**

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

Analyte (measurement parameter)	Test material (matrix)	Test technique
Aerobe bacteria (Staphylococci, Haemophilus, Neisseries)	Bacteria culture	with previous Color reaction

## Medical laboratory field: Virology

### Type of examination:

#### Ligand assays \*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Anti-HBc (antibodies)	Serum	Chemiluminescence immunoassay (CLIA)
Anti-HBc-IgM (antibodies)	Serum, Plasma	Chemiluminescence immunoassay (CLIA)
Anti-Hbe (antibodies)	Serum, Plasma	Chemiluminescence immunoassay (CLIA)
Anti-HBs (antibodies)	Serum	Chemiluminescence immunoassay (CLIA)
Cytomegalie (IgG-antibodies, avidity)	Serum	Chemiluminescence immunoassay (CLIA) Enzyme immunoassay (EIA)
Cytomegalie (IgM-antibodies)	Serum, Plasma	Enzyme immunoassay (EIA)
Epstein Barr Virus (EBNA-antibodies)	Serum	Enzyme immunoassay (EIA)
Epstein Barr Virus (IgG-, IgM-antibodies)	Serum, Plasma	Enzyme immunoassay (EIA), Immunoblot (Westernblot)
Tick-borne encephalitis (FSME) (IgG-, IgM-antibodies, spez. AI)	Serum, cerebrospinal fluid	Enzyme immunoassay (EIA)
HBeAg (antigen)	Serum, Plasma	Chemiluminescence immunoassay (CLIA)
HBsAg (antigen)	Serum, Plasma	Chemiluminescence immunoassay (CLIA)
Hepatitis C (HCV) (antibodies)	Serum, Plasma, cerebrospinal fluid	Enzyme immunoassay (EIA), Immunoblot (Westernblot)
Hepatitis D (antibodies)	Serum	Chemiluminescence immunoassay (CLIA)
Herpes simplex Virus Typ 1 (HSV1) (IgG-antibodies)	Serum	Immunoblot (Westernblot)
Herpes simplex Virus Typ 2 (HSV2) (IgG-antibodies)	Serum	Immunoblot (Westernblot)
HIV 1/2 (antigen/ antibodies)	Serum, Plasma	Enzyme immunoassay (EIA)
HIV 1/2 (antibodies)	Serum, Plasma	Immunoblot (Westernblot)
Human-T-Cell leukaemia (HTLV1+2) (IgG-antibodies)	Serum, Plasma	Chemiluminescence immunoassay (CLIA)
Intrathecal antibody determination (CMV, EBV, HSV, measles, mumps, rubella, VZV, FSME)	Serum, Plasma, cerebrospinal fluid	Enzyme immunoassay (EIA)
Measles virus (IgG-, IgM antibodies)	Serum, Plasma	Chemiluminescence immunoassay (CLIA)

Analyte (measurement parameter)	Test material (matrix)	Test technique
Mumps virus (IgG-, IgM antibodies)	Serum, Plasma	Chemiluminescence immunoassay (CLIA)
Parvovirus B19 (IgG-, IgM-antibodies)	Serum	Chemiluminescence immunoassay (CLIA)
Rubella virus (IgG-, IgM-antibodies)	Serum, Plasma	Chemiluminescence immunoassay
Varizella Zoster virus (VZV) (IgA-an IgM-antibodies)	Serum	Enzyme immunoassay (EIA); Chemiluminescence immunoassay

**Type of examination:**

**Molecular biological tests (amplification procedures) \*\***

Analyte (measurement parameter)	Test material (matrix)	Test technique
Adenovirus (DNA)	swab, cerebrospinal fluid, stool	Real-time PCR (fluorescence-labeled hybridization probes)
Monkey pox (DNA)	Swab	Real-time PCR (fluorescence-labeled hybridization probes)
BK-virus (DNA)	EDTA-blood, urine	Real-time PCR (fluorescence-labeled hybridization probes)
CMV (human cytomegalovirus) (DNA)	EDTA blood, urine, cerebrospinal fluid, BAL	Real-time PCR (fluorescence-labeled hybridization probes)
Epstein Barr virus (DNA)	EDTA blood, cerebrospinal fluid	Real-time PCR (fluorescence-labeled hybridization probes)
Hepatitis B virus (DNA)	EDTA-plasma	Real-time PCR (fluorescence-labeled hybridization probes)
Hepatitis C Virus (HCV)-Genotyp (RNA)	EDTA-plasma	Polymerasekettenreaktion und Line Probe Assay)
Hepatitis C Virus (HCV) (RNA)	EDTA-plasma	Real-time PCR (fluorescence-labeled hybridization probes)
Hepatitis E virus (RNA)	EDTA-plasma	Real-time PCR (fluorescence-labeled hybridization probes)
Herpes simplex type 1 and 2 (DNA)	Swab, cerebrospinal fluid, BAL, urine	Real-time PCR (fluorescence-labeled hybridization probes)
HIV-1 (RNA), HIV-2 (RNA), HCV- (RNA) and HBV- (DNA)	Serum, EDTA-Plasma	Real-time PCR (Fluoreszenz-markierte Hybridisierungssonden)
HIV-1 (RNA)	EDTA-plasma	Real-time PCR (fluorescence-labeled hybridization probes)
Human papillomavirus (high risk), (DNA)	Swab, ThinPrep	Real-time PCR (fluorescence-labeled hybridization probes)
Influenza A- and B- virus (RNA)	Swab, sputum, BAL	Real-time PCR (fluorescence-labeled hybridization probes)
Norovirus (RNA)	Stool	Real-time PCR (fluorescence-labeled hybridization probes)
Parvovirus B19 (DNA)	EDTA blood	Real-time PCR (fluorescence-labeled hybridization probes)
SARS-CoV-2	Swab, sputum	Real-time PCR (fluorescence-labeled hybridization probes)

Analyte (measurement parameter)	Test material (matrix)	Test technique
West Nile virus (RNA)	EDTA blood	Real-time PCR (fluorescence-labeled hybridization probes)
Zika virus (RNA)	EDTA-Plasma, Urine, Ejaculate	Real-time PCR (fluorescence-labeled hybridization probes)

## Medical laboratory field: Transfusion medicine

### Type of examination:

#### Agglutination tests \*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Antibody differentiation (pos. screening)	whole blood, EDTA blood, Lithium-Heparin blood, CPD-blood	Haemagglutination test
Blood group A (sub-groups)	whole blood, EDTA blood, Lithium-Heparin blood, CPD-blood	Haemagglutination test
Blood groups	whole blood, EDTA blood, Lithium-Heparin blood, CPD-blood	Haemagglutination test, Particle agglutination test
Direct Coombs test, differentiation	whole blood, EDTA blood, Lithium-Heparin blood, CPD-blood	Haemagglutination test
Irregular antibodies	whole blood, EDTA blood, Lithium-Heparin blood, CPD-blood	Haemagglutination test
Kell factor	whole blood, EDTA blood, Lithium-Heparin blood, CPD-blood	Haemagglutination test
Lewis antigen (a)	whole blood, EDTA blood, Lithium-Heparin blood, CPD-blood	Haemagglutination test
Lewis antigen (b)	whole blood, EDTA blood, Lithium-Heparin blood, CPD-blood	Haemagglutination test
M antigen	whole blood, EDTA blood, Lithium-Heparin blood, CPD-blood	Haemagglutination test
N antigen	whole blood, EDTA blood, Li-Heparin blood, CPD-Blood	Haemagglutination test
Rhesus factor	whole blood, EDTA blood, Lithium-Heparin blood, CPD-blood	Haemagglutination test, Particle agglutination test
Rhesus formula	whole blood, EDTA blood, Lithium-Heparin blood, CPD-blood	Haemagglutination test, Particle agglutination test
Rhesus factor	whole blood, EDTA blood, Lithium-Heparin blood, CPD-blood	Haemagglutination test, Particle agglutination test
Rhesus formula	whole blood, EDTA blood, Lithium-Heparin blood, CPD-blood	Haemagglutination test, Particle agglutination test