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Annex to the accreditation certificate D-ML-19241-01-00 according to DIN EN ISO 15189:2014

Valid from: 23.09.2022
Date of issue: 04.11.2022

Holder of accreditation certificate:

Laboratory Dr. Fenner und Kollegen
Medizinisches Versorgungszentrum für Labormedizin und Humangenetik GmbH
Bergstr. 14, 20095 Hamburg

The medical laboratory meets the minimal requirements of DIN EN ISO 15189:2014 and, if applicable, additional legal and normative requirements, including those in relevant sectoral schemes, in order to carry out the conformity assessment activities listed 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, cytogenetics)
Microbiology
Virology
Transfusion medicine

This document is a translation. The definitive version is the original German annex to the accreditation certificate.

Within the test areas marked with *, the laboratory is allowed the free choice of standardized or equivalent test methods, without requiring prior information and approval from the German Accreditation Body.
Within the examination fields marked with **, the medical laboratory is permitted to modify and further develop examination procedures without requiring prior information and approval from the DAkkS.
The test methods listed are examples. The laboratory has an up-to-date list of all test methods in the flexible accreditation area.

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 fields: Clinical chemistry

Type of examination:
Chromatography (gas chromatography mass spectrometry (GC-MS))**

Analyte (measurement parameter)	Test material (matrix)	Test technique
qualitative determination of amphetamines, benzodiazepines, opiates, methadon, tricyclic antidepressants, cocaine, designer drugs and other drugs	Urine	GC/MS

Type of examination:
Chromatography (High Performance Liquid Chromatography (HPLC))**

Analyte (measurement parameter)	Test material (matrix)	Test technique
5-Hydroxyindoleacetic Acid	24-hour urine	HPLC - ECD
Beta-carotene	Serum, EDTA-Plasma	HPLC - UV
HbA1c	EDTA blood	HPLC - VIS
Homocysteine	Serum, plasma (all additives except lithium heparin), citrated blood	HPLC - FLD
Homovanillinmandelic acid	24-hour urine	HPLC - ECD
Catecholamines (adrenaline, dopamine, norepinephrine)	24-hour urine	HPLC - ECD
Serotonin	Serum, EDTA blood	HPLC - ECD
Tryptophan	Serum	HPLC - FID
Vanillin mandelic acid	24h collection urine	HPLC - ECD
Vitamin A	Serum	HPLC - UV
Vitamin B1	EDTA blood	HPLC - FLD
Vitamin B2	EDTA blood	HPLC - FLD
Vitamin B6	Serum, EDTA-Plasma	HPLC - FLD
Vitamin C	EDTA plasma	HPLC - UV
Vitamin E	Serum	HPLC - UV

Type of examination:
Chromatography (High Performance Liquid Chromatography / Mass Spectrometry (LCMS/M

Analyte (measurement parameter)	Test material (matrix)	Test technique
10-OH-carbazepine	Serum, EDTA-Plasma	LCMS/MS
17-OH progesterone	Serum	LCMS/MS
Aldosterone	Serum	LCMS/MS
Amiodarone	Serum, EDTA-Plasma	LCMS/MS
Androstenedione	Serum	LCMS/MS
Aripiprazole	Serum, EDTA-Plasma	LCMS/MS
Brivaracetam	Serum, EDTA-Plasma	LCMS/MS
Buprenorphine, norbuprenorphine	Urine, serum	LCMS/MS
Carbamazepine	Serum, EDTA-Plasma	LCMS/MS
Carbamazepine diol	Serum, EDTA-Plasma	LCMS/MS
Carbamazepine epoxide	Serum, EDTA-Plasma	LCMS/MS
Citalopram	Serum, EDTA-Plasma	LCMS/MS
Clozapine, desmethylclozapine	Serum, EDTA-Plasma	LCMS/MS
Cortisol	Saliva	LCMS/MS
Cortisol	Serum	LCMS/MS
Cortisol	Urine	LCMS/MS
Cyclosporine	EDTA blood	LCMS/MS
Desmethylmesuximide	Serum, EDTA-Plasma	LCMS/MS
DHEA	Serum	LCMS/MS
Drugs	Saliva, serum/EDTA plasma, capillary blood	LCMS/MS
Duloxetine	Serum, EDTA-Plasma	LCMS/MS
Ethosuximide	Serum, EDTA-Plasma	LCMS/MS
Ethyl glucuronide	Urine, serum	LCMS/MS
Ethyl sulphate	Urine, serum	LCMS/MS
Everolimus	EDTA blood	LCMS/MS
Felbamate	Serum, EDTA-Plasma	LCMS/MS
Fluoxetine, desmethylfluoxetine	Serum, EDTA-Plasma	LCMS/MS
Fluvoxamine	Serum, EDTA-Plasma	LCMS/MS
Gabapentin	Serum, EDTA-Plasma	LCMS/MS
Haloperidol	Serum, EDTA-Plasma	LCMS/MS
Lacosamide	Serum, EDTA-Plasma	LCMS/MS
Lamotrigine	Serum, EDTA-Plasma	LCMS/MS
Levetiracetam	Serum, EDTA-Plasma	LCMS/MS
LSD	Urine	LCMS/MS
Metanephrine	Urine	LCMS/MS
Normetanephrine	Urine	LCMS/MS
Metanephrines / Normetanephrines	EDTA plasma	LCMS/MS
Methylmalonic acid	Serum, urine	LCMS/MS

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Analyte (measurement parameter)	Test material (matrix)	Test technique
Mirtazapine	Serum, EDTA-Plasma	LCMS/MS
Olanzapine, N-desmethylolanzapine	Serum, EDTA-Plasma	LCMS/MS
Oxcarbazepine	Serum, EDTA-Plasma	LCMS/MS
Paroxetine	Serum, EDTA-Plasma	LCMS/MS
Perampanel	Serum, EDTA-Plasma	LCMS/MS
Phenobarbital	Serum, EDTA-Plasma	LCMS/MS
Phosphatidylethanol	EDTA blood, citrated blood, capillary blood	LCMS/MS
Pregabalin	Serum, EDTA-Plasma	LCMS/MS
Pregabalin	Urine	LCMS/MS
Primidone	Serum, EDTA-Plasma	LCMS/MS
Quetiapine	Serum, EDTA-Plasma	LCMS/MS
Risperidone, 9-OH-risperidone	Serum, EDTA-Plasma	LCMS/MS
Rufinamide	Serum, EDTA-Plasma	LCMS/MS
Sertraline, N-desmethylsertraline	Serum, EDTA-Plasma	LCMS/MS
Sirolimus	EDTA blood	LCMS/MS
Stiripentol	Serum, EDTA-Plasma	LCMS/MS
Sulthiam	Serum, EDTA-Plasma	LCMS/MS
Tacrolimus	EDTA blood	LCMS/MS
THC-COOH, qualitative	Urine	LCMS/MS
Theophylline	Serum, EDTA-Plasma	LCMS/MS
Tiagabin	Serum, EDTA-Plasma	LCMS/MS
Topiramate	Serum, EDTA-Plasma	LCMS/MS
Venlafaxine, O-	Serum, EDTA-Plasma	LCMS/MS
Vigabatrin	Serum, EDTA-Plasma	LCMS/MS
Zonisamide	Serum, EDTA-Plasma	LCMS/MS
Valproate	Serum, EDTA-Plasma	LCMS/MS

Type of examination:
Flow cytometry (incl. determination of particle properties)*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Blood cells - erythrocytes - platelets	EDTA blood Citrate blood Thromboexact	Particle/cell counting using the impedance method (resistance change measurement) and further calculation
Blood cells - leukocytes - monocytes - lymphocytes - granulocytes - leukocyte precursors - eosinophils - normoblasts - platelets - basophils	EDTA blood	Flow cytometry using semiconductor lasers
Blood cells - leukocytes	CSF, punctate	Flow cytometry using semiconductor lasers
Hematocrit	EDTA blood	Particle/cell counting using the impedance method (resistance change measurement) and further calculation
MCV MCH MCHC	EDTA blood	Calculation from mean values of the erythrocyte measurement and the haemoglobin determination
Reticulocytes	EDTA blood	Flow cytometry using semiconductor lasers
Reticulocyte Hb (Ret-HE)	EDTA blood	Flow cytometry using semiconductor lasers

Type of examination:
Type of examination: Electrochemical examinations**

Analyte (measurement parameter)	Test material (matrix)	Test technique
Chloride	Serum, lithium heparin plasma, urine	Ion-sensitive electrodes
Potassium	Serum, lithium heparin plasma, urine	Ion-sensitive electrodes
Sodium	Serum, lithium heparin plasma, urine	Ion-sensitive electrodes
pH value (drug screening test)	Urine	pH meter

Type of examination: Electrophoresis*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Bence Jones protein	Urine	Zone electrophoresis
CDT (carbohydrase-deficient transferrin)	Serum	Capillary zone electrophoresis
Protein electrophoresis	Serum	Capillary zone electrophoresis
Paraproteins	Serum	Immunofixation electrophoresis
Paraproteins	Urine	Immunofixation electrophoresis

Type of examination: Coagulometry*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Derived fibrinogen	Citrated plasma	Determination of the concentration by measuring the change in turbidity in the coagulation test and comparing it with a standard curve
Current Partial thromboplastin time (aPTT)	Citrated plasma	Determination of the clotting time in seconds
APC resistance by measuring aPTT with/without addition of activated protein C (APC)	Citrated plasma	Determination of the clotting time and calculation of a ratio
Factor VIII (VIII: C) activity	Citrated plasma	Determination of the partial thromboplastin time after incubation with corresponding factor-deficient plasma
Lupus anticoagulant qualitative	Citrated plasma	Determination of the clotting time with a specific reagent and reference to a normal plasma
Protein C activity	Citrated plasma	Determination of protein C activity using a chromogenic substrate via the activation of protein C (absorption measurement)
Protein S activity	Citrated plasma	Determination by measuring the increase in turbidity
Thrombin time	Citrated plasma	Determination of the clotting time in seconds
Thromboplastin time (Quick)	Citrated plasma	Determination of the clotting time in seconds, based on a normal plasma

Type of examination:
Ligand assays*

Analyte (measurement parameter)	Test material (matrix)	Test technique
1.25 dihydroxyvitamin D	Serum, EDTA plasma, lithium heparin	CLIA
17-beta-oestradiol	Serum, heparin plasma, EDTA plasma	CLIA
ACTH	EDTA plasma	CLIA
Aldosterone	Serum, EDTA-Plasma	CLIA
Alpha faetoprotein	Serum, amniotic fluid	CLIA
Amphetamine	Urine	ELISA
Barbiturate	Urine	ELISA
Benzodiazepine	Urine	ELISA
Beta HCG	Serum	CLIA
CA 15-3	Serum	CLIA
CA 19-9	Serum	CLIA
CA125	Serum	CLIA
Cannabis	Urine	ELISA
CEA	Serum	CLIA
Cocaine	Urine	ELISA
Cortisol	Serum	CLIA
C-peptide	Serum	CLIA
DHEAS	Serum	CLIA
Digitoxin	Serum, heparin plasma	CLIA
Digoxin	Serum	CLIA
Ferritin	Serum, heparin plasma, EDTA plasma	CLIA
Folic acid	Serum	CLIA
FSH	Serum	CLIA
FT3	Serum	CLIA
FT4	Serum, heparin plasma, EDTA plasma	CLIA
Gentamicin	Serum, EDTA-Plasma	Fluorescence polarisation
HCG (total)	Serum	CLIA
Holotranscobalamin	Serum	ELISA
IGF (Somatomedin C)	Serum	CLIA
Insulin	Serum	CLIA
Luteotropic hormone, LH	Serum	CLIA
Methadone as EDDP	Urine	ELISA
NSE	Serum, CSF	CLIA
Opiates	Urine	ELISA
Ostasis	Serum	CLIA

Analyte (measurement parameter)	Test material (matrix)	Test technique
Pancreatic elastase	Stool	ELISA
Parathyroid hormone	Serum, heparin plasma, EDTA plasma	CLIA
Progesterone	Serum	CLIA
Prolactin	Serum	CLIA
PSA, free PSA	Serum	CLIA
Renin	EDTA plasma	CLIA
SHBG	Serum, lithium heparin plasma	CLIA
Somatotropic hormone (Human growth hormone)	Serum	CLIA
ß2 microglobulin	Serum, heparin plasma, EDTA plasma, citrated plasma	CLIA
Testosterone	Serum, heparin plasma, EDTA plasma	CLIA
Troponin I Ultra Highly Sensitive	Serum, heparin plasma	CLIA
TSH	Serum	CLIA
TSH receptor AK (TSI)	Serum	CLIA
Vitamin B12	Serum, heparin plasma	CLIA
Vitamin D	Serum, heparin plasma, EDTA plasma	CLIA

Type of examination: Microscopy*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Blood cells - leukocytes - erythrocytes	Cerebral spinal fluid (CSF)	Microscopic chamber count
Blood cells - monocytes - lymphocytes - granulocytes - leukocyte precursors - eosinophils - basophils - normoblasts - erythrocytes - platelets CSF cells	EDTA blood, CSF	Microscopic assessment of a stained blood smear or a cytocentrifugate (Pappenheim stain)
Bronchoalveolar cells	Bronchoalveolar lavage	Microscopic counting chamber count

Analyte (measurement parameter)	Test material (matrix)	Test technique
Differential blood count	CSF, bronchoalveolar lavage	Microscopic assessment of a stained blood smear or a cytocentrifugate (Pappenheim stain)
Urine sediment	Native urine	Automated microscopy

Type of examination:
Spectrometry (Inductively coupled plasma / mass spectrometry (ICP/MS))**

Analyte (measurement parameter)	Test material (matrix)	Test technique
Aluminium	Urine	ICPMS
Antimony	Urine, Serum	ICPMS
Arsenic	Urine, Serum	ICPMS
Bismuth	Serum	ICPMS
Lead	Urine, Serum, EDTA-Plasma	ICPMS
Cadmium	Urine, Serum, EDTA-Plasma	ICPMS
Calcium	Serum, Urine	ICPMS
Chrome	Urine, Serum, EDTA-Plasma	ICPMS
Iron	Urine	ICPMS
Iodine	Serum, Urine	ICPMS
Cobalt	Urine	ICPMS
Copper	Serum, Urine	ICPMS
Lithium	Serum	ICPMS
Magnesium	Urine, EDTA-Plasma	ICPMS
Manganese	Urine, Serum	ICPMS
Molybdenum	Urine, Serum	ICPMS
Potassium	Urine	ICPMS
Nickel	Urine, Serum	ICPMS
Palladium	Urine	ICPMS
Mercury	Urine	ICPMS
Selenium	Urine, Serum, EDTA-Plasma	ICPMS
Thallium	Urine	ICPMS
Vanadium	Serum	ICPMS
Zinc	Urine, Serum, EDTA-Plasma	ICPMS
Tin	Urine	ICPMS

Type of examination: Spectrometry (nephelometry)*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Albumin	Urine	Nephelometry
Albumin	CSF, serum	Nephelometry
Alpha-1 antitrypsin	Serum, heparin plasma, EDTA plasma	Nephelometry
Ceruloplasmin	Serum, heparin plasma	Nephelometry
Cystatin C	Serum, heparin plasma	Nephelometry
Haptoglobin	Serum, heparin plasma, EDTA plasma	Nephelometry
Soluble transferrin receptor	Serum, heparin plasma	Nephelometry
STFR ferritin	Serum, heparin plasma	Calculation sol. Transferrin receptor / Log ferritin

Type of examination: Spectrometry (photometry)**

Analyte (measurement parameter)	Test material (matrix)	Test technique
ACE	Serum, CSF	Photometry
Albumin	Serum, heparin plasma, EDTA plasma	Photometry
Alkaline phosphatase	Serum, lithium heparin plasma	Photometry
Ammonia	EDTA plasma	Photometry
Amylase	Serum, heparin plasma, urine	Photometry
Antithrombin	Citrated plasma	Photometry
Total bilirubin, direct and indirect	Serum, heparin plasma	Photometry
Bilirubin (newborn)	Serum	Photometry
Calcium	Serum, lithium heparin plasma	Photometry
Calcium	Serum	Flame photometry
Calcium	Urine	Flame photometry
Cholesterol	Serum, heparin plasma	Photometry
Cholinesterase CHE	Serum, heparin plasma	Photometry
Creatinine	Serum, lithium heparin plasma	Photometry
Creatinine	Urine	Photometry
Creatine kinase CK	Serum, lithium heparin plasma	Photometry
Creatine kinase CK-MB	Serum, heparin plasma, EDTA plasma	Photometry
Iron	Serum, lithium heparin plasma	Photometry
Ethanol	Serum / EDTA plasma / urine	Photometry
Gamma-GT	Serum, lithium heparin plasma	Photometry
Total protein	Serum, lithium heparin plasma	Photometry
Total protein	Urine, CSF	Photometry

Analyte (measurement parameter)	Test material (matrix)	Test technique
GLDH	Serum, heparin plasma, EDTA plasma	Photometry
Glucose	Serum, NaF plasma, fluoride citrated plasma, lithium heparin plasma, urine, CSF	Photometry
GOT	Serum, lithium heparin plasma	Photometry
GPT	Serum, lithium heparin plasma	Photometry
Haemoglobin	EDTA blood	Photometry
Uric acid	Serum, lithium heparin plasma, urine	Photometry
Urea	Serum, lithium heparin plasma, urine	Photometry
HBDH	Serum, heparin plasma, EDTA plasma	Photometry
HDL cholesterol	Serum, heparin plasma, EDTA plasma	Photometry
Lactate	NaF plasma, fluoride citrated plasma, lithium heparin plasma, EDTA plasma, CSF	Photometry
LDH	Serum, lithium heparin plasma	Photometry
LDL (direct measurement) + calculation	Serum, lithium heparin plasma	Photometry
Lipase	Serum, lithium heparin plasma	Photometry
Lithium	Serum	Flame photometry
Magnesium	Serum, lithium heparin plasma	Photometry
Phosphate, inorganic	Serum, lithium heparin plasma, urine	Photometry
Protein C activity	Citrated plasma	Photometry
Acid phosphatase	Serum	Photometry
Triglyceride	Serum, lithium heparin plasma	Photometry
Urine status	Urine	Photometry

Type of examination:
Spectrometry (Turbidimetry)*

Analyte (measurement parameter)	Test material (matrix)	Test technique
C-reactive protein	Serum, lithium heparin plasma	Turbidimetry
D-dimer concentration	Citrated plasma	Turbidimetry
Fibrinogen according to Claus	Citrated plasma	Turbidimetry
highly sensitive CRP	Serum, heparin plasma, EDTA plasma	Turbidimetry
Lipoprotein (a)	Serum, lithium heparin plasma	Turbidimetry
Rheumatoid factor	Serum	Turbidimetry

Analyte (measurement parameter)	Test material (matrix)	Test technique
Transferrin	Serum, lithium heparin plasma	Turbidimetry
Haemoglobin	Stool	Immunoturbidimetry

Type of examination: qualitative examination with visual evaluation*

Analyte (measurement parameter)	Test material (matrix)	Test technique
hCG detection (qualitative)	Urine	Test strip method (manual)
pH value	Urine	Colour change

Medical laboratory fields: Immunology

Type of examination: Flow cytometry*

Analyte (measurement parameter)	Test material (matrix)	Test technique
T lymphocyte populations, B lymphocytes, NK cells	EDTA-Blood, bronchoalveolar lavage	Flow cytometry

Type of examination: Electrophoresis*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Oligoclonal IgG	Serum and CSF	isoelectric focusing and immunofixation electrophoresis

Type of examination: Ligand assays**

Analyte (measurement parameter)	Test material (matrix)	Test technique
Ab against mutated citrullated vimentin	Serum, EDTA plasma	ELISA
Auto Ab. against CCP	Serum, heparin plasma, EDTA plasma	CLIA
Auto Ab. against: DFS70	Serum, heparin plasma, EDTA plasma, citrated plasma	ELISA
Auto Ab. against: Glomerular basement membrane	Serum, plasma (all additives)	FEIA
Auto Ab. against: Histones	Serum, heparin plasma, EDTA plasma, citrated plasma	ELISA
Auto Ab. against: Islet cells	Serum	ELISA
Auto Ab. against: Intrinsic factor	Serum, plasma (all additives)	FEIA
Auto Ab. against: Jo-1	Serum, plasma (all additives)	FEIA

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Analyte (measurement parameter)	Test material (matrix)	Test technique
Auto Ab. against: Lactoferrin, BPI, Cathepsin G, Elastase	Serum, EDTA-Plasma	ELISA
Auto Ab. against: LKM	Serum, heparin plasma, EDTA plasma, citrated plasma	ELISA
Auto Ab. against: M2	Serum, plasma (all additives)	FEIA
Auto Ab. against: Myeloperoxidase	Serum, plasma (all additives)	FEIA
Auto Ab. against: nDNS	Serum, plasma (all additives)	FEIA
Auto Ab. against: nRNP	Serum, plasma (all additives)	FEIA
Auto Ab. against: Nucleosomes	Serum, heparin plasma, EDTA plasma, citrated plasma	ELISA
Auto Ab. against: Parietal cells	Serum, plasma (all additives)	FEIA
Auto Ab. against: Proteinase 3	Serum, plasma (all additives)	FEIA
Auto Ab. against: Scl-70	Serum, plasma (all additives)	FEIA
Auto Ab. against: SLA/LP	Serum, heparin plasma, EDTA plasma, citrated plasma	ELISA
Auto Ab. against: Sm	Serum, plasma (all additives)	FEIA
Auto Ab. against: SSA 60	Serum, plasma (all additives)	FEIA
Auto Ab. against: SSB	Serum, plasma (all additives)	FEIA
Auto Ab. against: ssDNA	Serum, plasma (all additives)	FEIA
Beta amyloid	Cerebral spinal fluid (CSF)	ELISA
Calprotectin	Stool	CLIA
Calprotectin	Serum, EDTA-Plasma	FEIA
Cardiolipin IgG, IgM antibodies	Serum, plasma (all additives)	FEIA
Extractable nuclear Ab.	Serum, plasma (all additives)	FEIA
Ganglioside IgG & IgM	Serum	Immunoblot
Gliadin IgG/IgA Ab.	Serum, plasma (all additives)	FEIA
IgE specific	Serum, plasma (all additives)	FEIA
IgE, total	Serum, plasma (all additives)	FEIA
Interleukin-2 receptor, (sol.)	Serum	CLIA
Phospho-tau	Cerebral spinal fluid (CSF)	ELISA
Rheumatoid factor IgA, IgM	Serum, plasma (all additives)	FEIA
Thyroid Ab TPO/TAK	Serum, heparin plasma, EDTA plasma	CLIA
Tau protein	Cerebral spinal fluid (CSF)	ELISA
Transglutaminase IgA/IgG Ab.	Serum, plasma (all additives)	FEIA
TSH receptor Ab.	Serum	CLIA
β2-glycoprotein Ab.	Serum, heparin plasma, EDTA plasma, citrated plasma	ELISA

Type of examination: Microscopy*

Analyte (measurement parameter)	Test material (matrix)	Test technique
ANA	Serum, EDTA-Plasma	IIF
Auto Ab. against: Actin	Serum, EDTA-Plasma	IIF
Auto Ab. against: ANCA	Serum, EDTA-Plasma	IIF
Auto Ab. against: Endomysium	Serum, EDTA-Plasma	IIF
Auto Ab. against: smooth muscles	Serum, EDTA-Plasma	IIF
Auto Ab. against: Hu, Yo, Ri	Serum, EDTA-Plasma	IIF
Auto-Ab. against: Hu, Yo, Ri, Ma2, Ma1, Amphiphysin	Serum	Immunoblot
Auto Ab. against: iDNS	Serum, EDTA-Plasma	IIF

Type of examination: Spectrometry (immunonephelometry)*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Free light chains Kappa/Lambda	Serum, urine	Nephelometry
IgG, IgA, IgM	CSF, serum	Nephelometry
IgG1, IgG2, IgG3, IgG4 (IgG subclasses)	Serum, heparin plasma, EDTA plasma	Nephelometry

Type of examination: Spectrometry (Turbidimetry)*

Analyte (measurement parameter)	Test material (matrix)	Test technique
C3 complement	Serum	Turbidimetry
C4 complement	Serum	Turbidimetry
IgA	Serum, lithium heparin plasma	Turbidimetry
IgG	Serum, lithium heparin plasma	Turbidimetry
IgM	Serum, heparin plasma, EDTA plasma	Turbidimetry

Medical laboratory fields: Human genetics (cytogenetics)

Type of examination:
Chromosome analysis*

Analyte (measurement parameter)	Test material (matrix)	Test technique
constitutional chromosome set (detection of numerical and structural chromosome aberrations)	Heparinized peripheral blood and bone marrow aspirate	Chromosome banding analysis
constitutional chromosome set (detection of numerical and structural chromosome aberrations)	Heparinized peripheral blood and bone marrow aspirate, smear preparations (blood, bone marrow aspirate), buccal swabs	Fluorescence in situ hybridization (FISH) on fixed native or cultured cells (meta- and interphases)
constitutional chromosome set (detection of chromosomal imbalances)	EDTA blood	Comparative genome hybridization to oligonucleotide arrays
somatic chromosome set (detection of tumour-associated chromosome aberrations)	Heparinized peripheral blood and bone marrow aspirate	Chromosome banding analysis
somatic chromosome set (detection of tumour-associated chromosome aberrations)	Heparinized peripheral blood and bone marrow aspirate, smear preparations (blood, bone marrow aspirate), urothelial cells	Fluorescence in situ hybridization (FISH) on fixed native or cultured cells (meta- and interphases)
Hemizygous set of chromosomes in germ cells	Ejaculate	Fluorescence in situ hybridization (FISH) on decondensed sperm
11p11.1-q11.1/11q22 (D11Z1/ATM)	Fixed native or cultured cells, smear preparations	FISH with locus-specific probes at metaphases and interphases
11p15 (NUP98)	Fixed native or cultured cells, smear preparations	FISH with locus-specific probes at metaphases and interphases
11q13/14q32.2 (CCND1/IGH)	Fixed native or cultured cells, smear preparations	FISH with locus-specific probes at metaphases and interphases
11q22/17p13.1 (ATM/TP53)	Fixed native or cultured cells, smear preparations	FISH with locus-specific probes at metaphases and interphases
11q23 (KMT2A)	Fixed native or cultured cells, smear preparations	FISH with locus-specific probes at metaphases and interphases
12p11.1-q11.1/13q14/13q34 (D12Z3/RB1/LAMP1)	Fixed native or cultured cells, smear preparations	FISH with locus-specific probes at metaphases and interphases
12p13.2 (ETV6)	Fixed native or cultured cells, smear preparations	FISH with locus-specific probes at metaphases and interphases

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Analyte (measurement parameter)	Test material (matrix)	Test technique
13q14/17p13.1 (DLEU/TP53)	Fixed native or cultured cells, smear preparations	FISH with locus-specific probes at metaphases and interphases
13q14/21q22 (DSCR4)	Fixed native or cultured cells, smear preparations	FISH with locus-specific probes at metaphases and interphases
14q11.2 (TCR A/D)	Fixed native or cultured cells, smear preparations	FISH with locus-specific probes at metaphases and interphases
14q32.3 (IGH)	Fixed native or cultured cells, smear preparations	FISH with locus-specific probes at metaphases and interphases
15p11.2/15q11.2/15q24 (D15Z1/D15S10/PML)	Fixed native or cultured cells, smear preparations	FISH with locus-specific probes at metaphases
15p11.2/15q11.2/15q24 (D15Z1/SNRPN/PML)	Fixed native or cultured cells, smear preparations	FISH with locus-specific probes at metaphases
16q22 (CBFB)	Fixed native or cultured cells, smear preparations	FISH with locus-specific probes at metaphases and interphases
17p11.2/17q21.1 (SMS/RARA)	Fixed native or cultured cells, smear preparations	FISH with locus-specific probes at metaphases
17p13.1/17p11.1-q11.1 (TP53/D17Z1)	Fixed native or cultured cells, smear preparations	FISH with locus-specific probes at metaphases and interphases
18q21 (MALT1)	Fixed native or cultured cells, smear preparations	FISH with locus-specific probes at metaphases and interphases
1p32/1q21 (CDKN2C/CKS1B)	Fixed native or cultured cells, smear preparations	FISH with locus-specific probes at metaphases and interphases
20q12/20q13 (PTPRT/MYBL2)	Fixed native or cultured cells, smear preparations	FISH with locus-specific probes at metaphases and interphases
21q22.12 (RUNX1)	Fixed native or cultured cells, smear preparations	FISH with locus-specific probes at metaphases and interphases
21q22.13-q22.1 (D21S341/D21S342)	Fixed native or cultured cells, smear preparations	FISH with locus-specific probes at metaphases
22q11.2/22q13.3 (D22S75/SHANK3)	Fixed native or cultured cells, smear preparations	FISH with locus-specific probes at metaphases
22q11.2/22q13.3 (HIRA/ARSA)	Fixed native or cultured cells, smear preparations	FISH with locus-specific probes at metaphases
3q26 (MECOM)	Fixed native or cultured cells, smear preparations	FISH with locus-specific probes at metaphases and interphases
3q27-q28 (BCL2)	Fixed native or cultured cells, smear preparations	FISH with locus-specific probes at metaphases and interphases
4p16.3/14q32.3 (FGFR3/IGH)	Fixed native or cultured cells, smear preparations	FISH with locus-specific probes at metaphases and interphases
4p16.3/4p11.1-q11.1 (WHSC1/4cen)	Fixed native or cultured cells, smear preparations	FISH with locus-specific probes at metaphases
4q24 (TET2)	Fixed native or cultured cells, smear preparations	FISH with locus-specific probes at metaphases and interphases
6p21.1/14q32.3 (CCND3/IGH)	Fixed native or cultured cells, smear preparations	FISH with locus-specific probes at metaphases and interphases
6q21/6q23 (SEC63/MYB)	Fixed native or cultured cells, smear preparations	FISH with locus-specific probes at metaphases and interphases

Analyte (measurement parameter)	Test material (matrix)	Test technique
6q23 (MYB)	Fixed native or cultured cells, smear preparations	FISH with locus-specific probes at metaphases and interphases
7p11.1-q11.1/7q31 (D7Z1/D7S486)	Fixed native or cultured cells, smear preparations	FISH with locus-specific probes at metaphases and interphases
7q11.23/7q31 (ELN/D7S486)	Fixed native or cultured cells, smear preparations	FISH with locus-specific probes at metaphases
8q24 (MYC)	Fixed native or cultured cells, smear preparations	FISH with locus-specific probes at metaphases and interphases
9p12/9p11.1-q11.1 (CDKN2A/D9Z3)	Fixed native or cultured cells, smear preparations	FISH with locus-specific probes at metaphases and interphases
9p24.1 (JAK2)	Fixed native or cultured cells, smear preparations	FISH with locus-specific probes at metaphases and interphases
9q34/22q11.2 (ABL1/BCR)	Fixed native or cultured cells, smear preparations	FISH with locus-specific probes at metaphases and interphases
Xp11.1-q11.1/Xq13 (DXZ1/XIST)	Fixed native or cultured cells, smear preparations	FISH with locus-specific probes at metaphases and interphases
Xp22.3/Xp11.1-q11.1 (KAL/DXZ1)	Fixed native or cultured cells, smear preparations	FISH with locus-specific probes at metaphases
Xp22.31/Xp22.31/Xp11.1-q11.1 (STS/KAL/DXZ1)	Fixed native or cultured cells, smear preparations	FISH with locus-specific probes at metaphases
Xp22.33/Xp11.1-q11.1/Yq12 (SHOX/DXZ1/DYZ1)	Fixed native or cultured cells, smear preparations	FISH with locus-specific probes at metaphases and interphases
Yp11.1-q11.1/Yp11.1-q11.1/ 18p11.1-q11.1 (DXZ1/DYZ3/D18Z1)	Fixed native or cultured cells, smear preparations	FISH with locus-specific probes at metaphases and interphases
1/5/19p11.1-q11.1 (D1Z7/D5Z2/D19Z3)	Fixed native or cultured cells, smear preparations	FISH with centromere and satellite specific probes at metaphases and interphases
1q12 (D1Z1)	Fixed native or cultured cells, smear preparations	FISH with centromere and satellite specific probes at metaphases and interphases
2p11.1-q11.1 (D2Z2)	Fixed native or cultured cells, smear preparations	FISH with centromere and satellite specific probes at metaphases and interphases
3p11.1-q11.1 (D3Z3)	Fixed native or cultured cells, smear preparations	FISH with centromere and satellite specific probes at metaphases and interphases
4p11.1-q11.1 (D4Z1)	Fixed native or cultured cells, smear preparations	FISH with centromere and satellite specific probes at metaphases and interphases
6p11.1-q11.1 (D6Z1)	Fixed native or cultured cells, smear preparations	FISH with centromere and satellite specific probes at metaphases and interphases

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Analyte (measurement parameter)	Test material (matrix)	Test technique
7p11.1-q11.1 (D7Z1)	Fixed native or cultured cells, smear preparations	FISH with centromere and satellite specific probes at metaphases and interphases
8p11.1-q11.1 (D8Z2)	Fixed native or cultured cells, smear preparations	FISH with centromere and satellite specific probes at metaphases and interphases
9p11.1-q11.1 (D9Z3)	Fixed native or cultured cells, smear preparations	FISH with centromere and satellite specific probes at metaphases and interphases
10p11.1-q11.1 (D10Z1)	Fixed native or cultured cells, smear preparations	FISH with centromere and satellite specific probes at metaphases and interphases
11p11.1-q11.1 (D11Z1)	Fixed native or cultured cells, smear preparations	FISH with centromere and satellite specific probes at metaphases and interphases
12p11.1-q11.1 (D12Z3)	Fixed native or cultured cells, smear preparations	FISH with centromere and satellite specific probes at metaphases and interphases
13/21p11.1-q11.1 (D13Z1/D21Z1)	Fixed native or cultured cells, smear preparations	FISH with centromere and satellite specific probes at metaphases and interphases
14/22p11.1-q11.1 (D14Z1/D22Z1)	Fixed native or cultured cells, smear preparations	FISH with centromere and satellite specific probes at metaphases and interphases
15p11.1-q11.1 (D15Z4)	Fixed native or cultured cells, smear preparations	FISH with centromere and satellite specific probes at metaphases and interphases
15p11.2 (D15Z1)	Fixed native or cultured cells, smear preparations	FISH with centromere and satellite specific probes at metaphases and interphases
16p11.1-q11.1 (D16Z2)	Fixed native or cultured cells, smear preparations	FISH with centromere and satellite specific probes at metaphases and interphases
17p11.1-q11.1 (D17Z1)	Fixed native or cultured cells, smear preparations	FISH with centromere and satellite specific probes at metaphases and interphases
18p11.1-q11.1 (D18Z1)	Fixed native or cultured cells, smear preparations	FISH with centromere and satellite specific probes at metaphases and interphases

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Analyte (measurement parameter)	Test material (matrix)	Test technique
20p11.1-q11.1 (D20Z1)	Fixed native or cultured cells, smear preparations	FISH with centromere and satellite specific probes at metaphases and interphases
Xp11.1-q11.1 (DXZ1)	Fixed native or cultured cells, smear preparations	FISH with centromere and satellite specific probes at metaphases and interphases
Yp11.1-q11.1 (DYZ3)	Fixed native or cultured cells, smear preparations	FISH with centromere and satellite specific probes at metaphases and interphases
Yq12 (DYZ1)	Fixed native or cultured cells, smear preparations	FISH with centromere and satellite specific probes at metaphases and interphases
Xp11.1-q11.1/Yp11.1-q11.1 (DXZ1/DYZ3)	Fixed native or cultured cells, smear preparations	FISH with centromere and satellite specific probes at metaphases and interphases
1p/1q (wcp)	Fixed cultured cells	FISH with whole chromosome painting probes
2p/2q (wcp)	Fixed cultured cells	FISH with whole chromosome painting probes
3p/3q (wcp)	Fixed cultured cells	FISH with whole chromosome painting probes
4p/4q (wcp)	Fixed cultured cells	FISH with whole chromosome painting probes
5p/5q (wcp)	Fixed cultured cells	FISH with whole chromosome painting probes
6p/6q (wcp)	Fixed cultured cells	FISH with whole chromosome painting probes
7p/7q (wcp)	Fixed cultured cells	FISH with whole chromosome painting probes
8p/8q (wcp)	Fixed cultured cells	FISH with whole chromosome painting probes
9p/9q (wcp)	Fixed cultured cells	FISH with whole chromosome painting probes
10p/10q (wcp)	Fixed cultured cells	FISH with whole chromosome painting probes
11p/11q (wcp)	Fixed cultured cells	FISH with whole chromosome painting probes
12p/12q (wcp)	Fixed cultured cells	FISH with whole chromosome painting probes
13q (wcp)	Fixed cultured cells	FISH with whole chromosome painting probes
14q (wcp)	Fixed cultured cells	FISH with whole chromosome painting probes

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Analyte (measurement parameter)	Test material (matrix)	Test technique
15q (wcp)	Fixed cultured cells	FISH with whole chromosome painting probes
16p/16q (wcp)	Fixed cultured cells	FISH with whole chromosome painting probes
17p/17q (wcp)	Fixed cultured cells	FISH with whole chromosome painting probes
18p/18q (wcp)	Fixed cultured cells	FISH with whole chromosome painting probes
19p/19q (wcp)	Fixed cultured cells	FISH with whole chromosome painting probes
20p/20q (wcp)	Fixed cultured cells	FISH with whole chromosome painting probes
21q (wcp)	Fixed cultured cells	FISH with whole chromosome painting probes
22q (wcp)	Fixed cultured cells	FISH with whole chromosome painting probes
Xp/Xq (wcp)	Fixed cultured cells	FISH with whole chromosome painting probes
Yp/Yq (wcp)	Fixed cultured cells	FISH with whole chromosome painting probes
Complete chromosomal complement	Fixed cultured cells	M-FISH
1p/1q (pcp)	Fixed cultured cells	FISH with region-specific painting probes
2p/2q (pcp)	Fixed cultured cells	FISH with region-specific painting probes
3p/3q (pcp)	Fixed cultured cells	FISH with region-specific painting probes
4p/4q (pcp)	Fixed cultured cells	FISH with region-specific painting probes
5p/5q (pcp)	Fixed cultured cells	FISH with region-specific painting probes
6p/6q (pcp)	Fixed cultured cells	FISH with region-specific painting probes
7p/7q (pcp)	Fixed cultured cells	FISH with region-specific painting probes
8p/8q (pcp)	Fixed cultured cells	FISH with region-specific painting probes
9p/9q (pcp)	Fixed cultured cells	FISH with region-specific painting probes
10p/10q (pcp)	Fixed cultured cells	FISH with region-specific painting probes
11p/11q (pcp)	Fixed cultured cells	FISH with region-specific painting probes
12p/12q (pcp)	Fixed cultured cells	FISH with region-specific painting probes

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Analyte (measurement parameter)	Test material (matrix)	Test technique
13q (pcp)	Fixed cultured cells	FISH with region-specific painting probes
14q (pcp)	Fixed cultured cells	FISH with region-specific painting probes
15q (pcp)	Fixed cultured cells	FISH with region-specific painting probes
16p/16q (pcp)	Fixed cultured cells	FISH with region-specific painting probes
17p/17q (pcp)	Fixed cultured cells	FISH with region-specific painting probes
18p/18q (pcp)	Fixed cultured cells	FISH with region-specific painting probes
19p/19q (pcp)	Fixed cultured cells	FISH with region-specific painting probes
20p/20q (pcp)	Fixed cultured cells	FISH with region-specific painting probes
21q (pcp)	Fixed cultured cells	FISH with region-specific painting probes
22q (pcp)	Fixed cultured cells	FISH with region-specific painting probes
Xp/Xq (pcp)	Fixed cultured cells	FISH with region-specific painting probes
Yp/Yq (pcp)	Fixed cultured cells	FISH with region-specific painting probes
acro-p-arm (13,14,15,21, 22p11.2-p12)	Fixed cultured cells	FISH with region-specific painting probes
1pter	Fixed cultured cells	FISH with subtelomere-specific probes
2pter	Fixed cultured cells	FISH with subtelomere-specific probes
3pter	Fixed cultured cells	FISH with subtelomere-specific probes
4pter	Fixed cultured cells	FISH with subtelomere-specific probes
5pter	Fixed cultured cells	FISH with subtelomere-specific probes
6pter	Fixed cultured cells	FISH with subtelomere-specific probes
7pter	Fixed cultured cells	FISH with subtelomere-specific probes
8pter	Fixed cultured cells	FISH with subtelomere-specific probes
9pter	Fixed cultured cells	FISH with subtelomere-specific probes

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Analyte (measurement parameter)	Test material (matrix)	Test technique
10pter	Fixed cultured cells	FISH with subtelomere-specific probes
11pter	Fixed cultured cells	FISH with subtelomere-specific probes
12pter	Fixed cultured cells	FISH with subtelomere-specific probes
16pter	Fixed cultured cells	FISH with subtelomere-specific probes
17pter	Fixed cultured cells	FISH with subtelomere-specific probes
18pter	Fixed cultured cells	FISH with subtelomere-specific probes
19pter	Fixed cultured cells	FISH with subtelomere-specific probes
20pter	Fixed cultured cells	FISH with subtelomere-specific probes
XYpter	Fixed cultured cells	FISH with subtelomere-specific probes
1qter	Fixed cultured cells	FISH with subtelomere-specific probes
2qter	Fixed cultured cells	FISH with subtelomere-specific probes
3qter	Fixed cultured cells	FISH with subtelomere-specific probes
4qter	Fixed cultured cells	FISH with subtelomere-specific probes
5qter	Fixed cultured cells	FISH with subtelomere-specific probes
6qter	Fixed cultured cells	FISH with subtelomere-specific probes
7qter	Fixed cultured cells	FISH with subtelomere-specific probes
8qter	Fixed cultured cells	FISH with subtelomere-specific probes
9qter	Fixed cultured cells	FISH with subtelomere-specific probes
10qter	Fixed cultured cells	FISH with subtelomere-specific probes
11qter	Fixed cultured cells	FISH with subtelomere-specific probes
12qter	Fixed cultured cells	FISH with subtelomere-specific probes
13qter	Fixed cultured cells	FISH with subtelomere-specific probes
14qter	Fixed cultured cells	FISH with subtelomere-specific probes

Analyte (measurement parameter)	Test material (matrix)	Test technique
15qter	Fixed cultured cells	FISH with subtelomere-specific probes
16qter	Fixed cultured cells	FISH with subtelomere-specific probes
17qter	Fixed cultured cells	FISH with subtelomere-specific probes
18qter	Fixed cultured cells	FISH with subtelomere-specific probes
19qter	Fixed cultured cells	FISH with subtelomere-specific probes
20qter	Fixed cultured cells	FISH with subtelomere-specific probes
21qter	Fixed cultured cells	FISH with subtelomere-specific probes
22qter	Fixed cultured cells	FISH with subtelomere-specific probes
XYqter	Fixed cultured cells	FISH with subtelomere-specific probes

Medical laboratory fields: Human genetics (molecular human genetics)

Type of examination:
Molecular biological examinations (amplification methods)**

Analyte (measurement parameter)	Test material (matrix)	Test technique
ABCD1	EDTA blood	PCR+Sanger sequencing
Adenomatous polyposis (APC [MIM*611731], MUTYH [MIM*604933])	EDTA blood	sequence capture (Illumina Nextera), Sequencing-by-synthesis
Adrenoleukodystrophy (ABCD1 [MIM*300371])	EDTA blood	sequence capture (Illumina Nextera), Sequencing-by-synthesis
AFG3L2	EDTA blood	PCR+SPCR+Sanger sequencing + MLPA
Alpha1 antitrypsin genotyping	EDTA blood	Fluorescence-labelled hybridization probes (real-time PCR)
APC	EDTA blood	PCR+Sanger sequencing + MLPA
ATL1 (SPG3A)	EDTA blood	PCR+Sanger sequencing+ MLPA
ATM	EDTA blood	PCR+Sanger sequencing+ MLPA
ATP7B	EDTA blood	PCR+Sanger sequencing + MLPA
ATXN1 (SCA1, Repeat)	EDTA blood	PCR+fragment analysis

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Analyte (measurement parameter)	Test material (matrix)	Test technique
ATXN2 gene (SCA2, Repeat)	EDTA blood	PCR+fragment analysis
ATXN3 gene (SCA3, Repeat)	EDTA blood	PCR+fragment analysis
ATXN7 gene (SCA7, Repeat)	EDTA blood	PCR+fragment analysis
Azoospermia factor (y-chromosome microdeletions)	EDTA blood	Allele-specific PCR with size-specific DNA fragment analysis in agarose gel
bcr/abl chromosome translocation t(9;22)	EDTA blood	Fluorescence-labelled hybridization probes (real-time PCR)
BMPR1A	EDTA blood	PCR+Sanger sequencing+ MLPA
BRCA1 gene	EDTA blood	PCR+Sanger sequencing+ MLPA
BRCA2 gene	EDTA blood	PCR+Sanger sequencing+ MLPA
BRIP1	EDTA blood	PCR+Sanger sequencing+ MLPA
BSCL2 (SPG17)	EDTA blood	PCR+Sanger sequencing
CACNA1A1 gene (SCA6, Repeat)	EDTA blood	PCR+fragment analysis
CDH1	EDTA blood	PCR+Sanger sequencing
CHEK2	EDTA blood	PCR+Sanger sequencing
CYP21A2 gene	EDTA blood	PCR+Sanger sequencing, MLPA
CYP7B1 (SPG5a)	EDTA blood	PCR+Sanger sequencing
Cystic fibrosis (CFTR [MIM*602421])	EDTA blood	sequence capture (Illumina Nextera), Sequencing-by-synthesis
DMD gene (DMD/BMD Dup/Del)	EDTA blood	PCR+MLPA
DMPK gene (MD1, Repeat)	EDTA blood	PCR+fragment analysis
ENG	EDTA blood	PCR+Sanger sequencing + MLPA
Hereditary nonpolyposis colon cancer (HNPCC), Lynch syndrome (MSH2 [MIM*609309], MSH6 [MIM*600678], MLH1 [MIM*120436], PMS2 [MIM*600259], EPCAM [MIM*185535])	EDTA blood	sequence capture (Illumina Nextera), Sequencing-by-synthesis
Exon 14 skipping in the DPD gene	EDTA blood	Fluorescence-labelled hybridization probes (real-time PCR)
Factor II gene (G20210A) in hereditary thrombophilia	EDTA blood	Fluorescence-labelled hybridization probes (real-time PCR)
Factor V gene (G1691A) in hereditary thrombophilia	EDTA blood	Fluorescence-labelled hybridization probes (real-time PCR)

Analyte (measurement parameter)	Test material (matrix)	Test technique
familial breast cancer: ATM (OMIM 607585), BRCA1 (OMIM 133705), BRCA2 (OMIM 600185), BRIP1 (OMIM 605882), CDH1 (OMIM 192090), CHEK2 (OMIM 604373), NBN (OMIM 602667), PALB2 (OMIM 610355), PTEN (OMIM 601728), RAD51C (OMIM 602774), RAD51D (OMIM 602954), STK11 (OMIM 602216), TP53 (OMIM 191170)	EDTA blood	sequence capture (Illumina Nextera), Sequencing-by-synthesis
FGF14	EDTA blood	PCR+Sanger sequencing
FMR1 gene (FRAXA, FXTAS, POI, Repeat)	EDTA blood	PCR+repeat analysis
FXN gene (FRDA, Repeat)	EDTA blood	PCR+fragment analysis
hereditary ataxias (PLEKHG4 (SCA4) [MIM*609526], SPTBN2 (SCA5) [MIM*604985], TTBK2 (SCA11) [MIM*611695], KCNC3 (SCA13) [MIM*176264], PRKCG (SCA14) [MIM*176980], ITPR1 (SCA15) [MIM*147265], FGF14 (SCA27) [MIM*601515], AFG3L2 (SCA28) [MIM*604581], SYNE1 [MIM*608441)	EDTA blood	sequence capture (Illumina Nextera), Sequencing-by-synthesis
HFE genotyping (C282Y, H63D) in hereditary hemochromatosis	EDTA blood	Fluorescence-labelled hybridization probes (real-time PCR)
HLA -B*27 genotyping	EDTA blood	Melting point analysis of the amplification products with SYBR Green
HLA-B*5701	EDTA blood	Allele-specific PCR with size-specific DNA fragment analysis in agarose gel
HSPD1 (SPG13)	EDTA blood	PCR+Sanger sequencing
HTT gene (HD, Repeat)	EDTA blood	PCR+fragment analysis
ITPR1	EDTA blood	PCR+Sanger sequencing
KCNC3	EDTA blood	PCR+Sanger sequencing
KIAA0196 (SPG8)	EDTA blood	PCR+Sanger sequencing
KIAA1840 (SPG11)	EDTA blood	PCR+Sanger sequencing + MLPA
KIF5A (SPG10)	EDTA blood	PCR+Sanger sequencing

Analyte (measurement parameter)	Test material (matrix)	Test technique
colorectal carcinoma (APC [MIM*611731], BMPR1A [MIM*601299], CDH1 [MIM*192090], CHEK2 [MIM*604373], ENG [MIM*131195], EPCAM [MIM*185535], MLH1 (MIM*120436], MSH2 [MIM*609309], MSH6 [MIM*600678], MUTYH [MIM*604933], PMS2 [MIM*600259], PTEN [MIM*601728], SMAD4 [MIM*600993], STK11 [MIM*602216])	EDTA blood	sequence capture (Illumina Nextera), Sequencing-by-synthesis
Congenital/Cyclic Neutropenia (ELANE [MIM*185535])	EDTA blood	sequence capture (Illumina Nextera), Sequencing-by-synthesis
MEFV gene	EDTA blood	PCR+sequencing
MLH1 gene	EDTA blood	PCR+sequencing + MLPA
Wilson's disease (ATP7B [MIM*606882])	EDTA blood	sequence capture (Illumina Nextera), Sequencing-by-synthesis
MSH2 gene	EDTA blood	PCR+sequencing + MLPA
MSH6 gene	EDTA blood	PCR+sequencing + MLPA
Mutations in the CFTR gene; Cystic fibrosis (mucoviscidosis)	EDTA blood	Amplification Refractory Mutation System (ARMS)
MUTYH	EDTA blood	PCR+Sanger sequencing + MLPA
MVK gene	EDTA blood	PCR+sequencing
N-acetyltransferase 2 (NAT2) gene polymorphism	EDTA blood	Fluorescence-labelled hybridization probes (real-time PCR)
NIPA1 (SPG6)	EDTA blood	PCR+Sanger sequencing + MLPA
NLRP3	EDTA blood	PCR+Sanger sequencing
NOTCH3	EDTA blood	PCR+Sanger sequencing
NPC1	EDTA blood	PCR+Sanger sequencing + MLPA
NPC2	EDTA blood	PCR+Sanger sequencing + MLPA
Pal (4G/5G) polymorphism	EDTA blood	Fluorescence-labelled hybridization probes (real-time PCR)
PALB2	EDTA blood	PCR+Sanger sequencing + MLPA
PGN (SPG7)	EDTA blood	PCR+Sanger sequencing + MLPA
PLEKHG4	EDTA blood	PCR+Sanger sequencing
PMP22-Gen	EDTA blood	PCR+Sanger sequencing + MLPA
PMS2	EDTA blood	PCR+Sanger sequencing + MLPA
Polymorphic variants (M1,T1) of the GST gene	EDTA blood	Allele-specific PCR with size-specific DNA fragment analysis in agarose gel

Analyte (measurement parameter)	Test material (matrix)	Test technique
Polymorphic variants (P1) of the GST gene	EDTA blood	Fluorescence-labelled hybridization probes (real-time PCR)
Primary (hereditary) lactose intolerance	EDTA blood	Fluorescence-labelled hybridization probes (real-time PCR)
PRKCG	EDTA blood	PCR+Sanger sequencing
PTEN	EDTA blood	PCR+Sanger sequencing + MLPA
RAD51C	EDTA blood	PCR+Sanger sequencing + MLPA
RAD51D	EDTA blood	PCR+Sanger sequencing + MLPA
REEP1 (SPG31)	EDTA blood	PCR+Sanger sequencing + MLPA
SCA17	EDTA blood	PCR+fragment analysis
SHOX	EDTA blood	PCR+Sanger sequencing + MLPA
SLC6A4 genotyping	EDTA blood	Fluorescence-labeled hybridization probes (real-time PCR) and size-specific DNA fragment analysis in agarose gel
SMAD4	EDTA blood	PCR+Sanger sequencing + MLPA
SMN1 gene, (SMA, Del)	EDTA blood	PCR+MLPA
SPAST (SPG4)	EDTA blood	PCR+Sanger sequencing + MLPA
SPINK1	EDTA blood	PCR+Sanger sequencing + MLPA
SPTBN2	EDTA blood	PCR+Sanger sequencing
STK11	EDTA blood	PCR+Sanger sequencing + MLPA
Superoxide dismutase 2 polymorphism (Ala16Val)	EDTA blood	Fluorescence-labelled hybridization probes (real-time PCR)
TNFRSF1A gene	EDTA blood	PCR+sequencing
TP53	EDTA blood	PCR+Sanger sequencing + MLPA
TPMT - Genotyping	EDTA blood	Fluorescence-labelled hybridization probes (real-time PCR)
TTBK2	EDTA blood	PCR+Sanger sequencing
VHL	EDTA blood	PCR+Sanger sequencing + MLPA
ZFYVE26 (SPG15)	EDTA blood	PCR+Sanger sequencing
ZFYVE27 (SPG33)	EDTA blood	PCR+Sanger sequencing

Medical laboratory fields: Microbiology

Type of examination: Agglutination tests*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Anti-staphylolysin titre	Serum	Direct agglutination
Haemophilus influenzae capsule type B	Pure culture isolates	Gruber agglutination
VDRL	Serum, EDTA-Plasma	Direct agglutination

Type of examination:
Chromatography (immunochromatography (IC))*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Clostridioides difficile antigen and toxin	Stool	Immunochromatography
MRSA (PBP2a)	Pure culture isolates	Immunochromatography

Type of examination:
Susceptibility testing of bacteria, fungi*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Aerobic and facultative anaerobic fast-growing bacteria	Pure culture isolates	Agar diffusion, carrier-bound gradient diffusion
Aerobic and facultative anaerobic fast-growing bacteria	Pure culture isolates	Broth dilution method as minimum inhibitory concentration (MIC)/break point
Anaerobic bacteria	Pure culture isolates	carrier-bound gradient diffusion
Beta lactamase former	Pure culture isolates	Biochemical reaction to carrier substance with antibiotics
Candida spp.	Pure culture isolates	Broth dilution method as minimum inhibitory concentration (MIC)/break point
ESBL	Pure culture isolates	Broth dilution method as minimum inhibitory concentration (MIC)/break point, agar diffusion
MRGN	Pure culture isolates	Broth dilution method as minimum inhibitory concentration (MIC)/break point, agar diffusion
MRSA	Pure culture isolates	Broth dilution method as minimum inhibitory concentration (MIC)/break point, agar diffusion
Mycoplasma hominis and Ureaplasma urealyticum	Urine, ejaculate	Broth dilution method as minimum inhibitory concentration (MIC)/break point
VRE	Pure culture isolates	Broth dilution method as minimum inhibitory concentration (MIC)/break point, agar diffusion

Type of examination: Germ identification*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Bacteria, fungi	Culture	mass spectrometric pathogen differentiation (MALDI-TOF-MS)
Bacteria, fungi	Culture	Biochemically complex
Bacteria	Culture	Biochemically complex
Mycoplasma hominis and Ureaplasma urealyticum	Culture	Biochemically complex
Sprout cells, dermatophytes, moulds	Culture	Microscopy

Type of examination: Cultural examinations*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Aerobic and facultatively anaerobic growing bacteria	Body fluids, smears, aspirates, tissue	Cultivation specific and non-specific, partly: CO2-enriched, aerobic, micro-aerobic atmosphere, temperature dependent
Anaerobic bacteria	Body fluids, smears, aspirates, tissue	Cultivation specific and non-specific, anaerobic atmosphere
Blood cultures	Blood cultures, aspirates, CSF	Fully mechanized blood culture process
Detection of bacterial growth-inhibiting substances (inhibitors)	Urine, body fluids	inhibition of growth of Bacillus spores (inhibitor detection test)
Mycoplasma hominis and Ureaplasma urealyticum	Urine, ejaculate	Cultivation specific
Mycobacteria	resp. material, urine, stool, punctate, tissue	Cultivation specific
Sprout cells, dermatophytes and moulds	Body fluids, smears, aspirates, tissue	Cultivation specific and non-specific, temperature dependent

Type of examination: Ligand assays*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Bordetella pertussis toxin IgG	Serum, heparin plasma, EDTA plasma, citrated plasma	ELISA
Borrelia burgdorferi IgG/ IgM	Serum, EDTA-Plasma	Immunoblot
Borrelien IgG-, IgM Ab.	Serum, heparin plasma, EDTA plasma, citrated plasma	ELISA

Analyte (measurement parameter)	Test material (matrix)	Test technique
Borrelien IgG/IgM Ab.	CSF and serum	ELISA
Campylobacter IgA Ab.	Serum, heparin plasma, EDTA plasma, citrated plasma	ELISA
Chlamydia pneumoniae IgG-, IgA Ab.	serum	ELISA
Chlamydia trachomatis IgG-, IgA Ab.	serum	ELISA
Diphtheria - Ab.	Serum, heparin plasma, EDTA plasma, citrated plasma	ELISA
Entamoeba histolytica antigen	Stool	ELISA
Giardia lamblia antigen	Stool	ELISA
Helicobacter pylori antigen	Stool	ELISA
Legionella quick test	Urine	Immunofluorescence
Lues- IgG-, IgM Ab.	Serum, heparin plasma, EDTA plasma, citrated plasma, CSF	ELISA
Mycoplasma pneumoniae IgG, IgA, IgM Ab.	Serum, heparin plasma, EDTA plasma, citrated plasma	ELISA
Tetanus Antitoxin IgG	Serum, heparin plasma, EDTA plasma, citrated plasma	ELISA
Toxoplasmose IgG- and IgM Ab.	Serum, heparin plasma, EDTA plasma	CLIA
Treponema pallidum IgG/IgM	Serum, EDTA-Plasma	Immunoblot
Treponema Screen	Serum, heparin plasma, EDTA plasma, citrated plasma	CLIA
Verotoxin (EHEC)	Stool	ELISA
Yersinien IgG-, IgA Ab.	Serum, EDTA-Plasma	Immunoblot

Type of examination: Microscopy*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Bacteria	Body fluids, smears, aspirates, tissue	Bright field microscopy after staining with dyes
Mycobacteria	resp. material	Bright field microscopy after staining with dyes
Parasites	Stool, cellophane tape imprint	Bright field microscopy without and after staining with dyes
plasmodium spec. (Malaria)	EDTA blood, capillary blood	Microscopy
Sprout cells, dermatophytes and moulds	Isolate in pure culture	Bright field microscopy without and after staining with dyes

Type of examination:
Molecular biological examinations (amplification methods)*

Analyte (measurement parameter)	Test material (matrix)	Test technique
16s rDNA sequencing	Bacterial colonies on agar plates, bacterial suspension	PCR+sequencing
18s rDNA sequencing	Fungal colonies on agar plates, fungal suspension	PCR+sequencing
B. pertussis/parapertussis	Swab, BAL	isothermal amplification
Chlamydia trachomatis and Neisseria gonorrhoeae DNA, qualitative	Swab, urine	Nucleic acid amplification with parallel detection of amplicons via probe hybridization
Chlamydophila pneumoniae and Mycoplasma pneumoniae DNA qualitative	Swab, tracheal secretion, BAL	Nucleic acid amplification with parallel detection of amplicons via probe hybridization
Gastro bacteria	Stool	Real time PCR
Methicillin Resistant S. aureus (MRSA) DNA Qualitative	Smear	Nucleic acid amplification with parallel detection of amplicons via probe hybridization
Mycobacterium tuberculosis complex and rifampicin-mediated mutation in the rpoB gene	Sputum, BAL, liquor, culture material	Nucleic acid amplification with parallel detection of amplicons via probe hybridization
Mycobacterium tuberculosis complex	resp. materials, culture	PCR/ probe melting point determination
Periodontal pathogen DNA qualitative	Paper point from gingival pocket	Nucleic acid amplification Detection of amplicons via solid phase probe hybridization
Pneumocystis jirovecii	Swab, tracheal secretion, BAL	Nucleic acid amplification with parallel detection of amplicons via probe hybridization
Sexually-transmitted infections (STI) Chlamydia trachomatis, N. gonorrhoeae, T.vaginalis, U.urealyticum, U.parvum, M.hominis, M.genitalium	Swab, urine	Nucleic acid amplification with parallel detection of amplicons via probe hybridization (Multiplex-PCR)

Type of examination:
Qualitative examinations (simple) with visual evaluation

Analyte (measurement parameter)	Test material (matrix)	Test technique
Differentiation of catalase-positive / catalase-negative bacteria	Single colony	biochemically orienting (catalase)
Differentiation of coagulase-positive / coagulase-negative bacteria	Single colony	biochemically simple (coagulase)
Differentiation of oxidase-positive / oxidase-negative bacteria	Single colony	biochemically orienting (oxidase)

Type of examination:
Spectrometry (Turbidimetry)*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Anti-streptolysin titer	Serum, heparin plasma, EDTA plasma	Turbidimetry

Type of examination:
Cell function tests*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Release of IFNg after stimulation with M. tuberculosis antigens	Blood in Li-Heparin tubes	Cytokine release, measurement of cytokine by ELISA

Medical laboratory fields: Virology

Type of examination:
Ligand assays**

Analyte (measurement parameter)	Test material (matrix)	Test technique
Adenovirus AG	Stool	ELISA
Adenovirus IgG/IgA Ab.	Serum, heparin plasma, EDTA plasma, citrated plasma	ELISA
CMV IgG/IgM Ab.	Serum, heparin plasma, EDTA plasma, citrated plasma	ELISA
Coxsackie IgG, IgA Ab.	Serum, heparin plasma, EDTA plasma, citrated plasma	ELISA
Coxsackie IgG Ab.	CSP, serum	ELISA
EBV: EBNA IgG Ab.	Serum, heparin plasma, EDTA plasma, citrated plasma	ELISA
EBV: VCA IgG Ab.	Serum, heparin plasma, EDTA plasma, citrated plasma	ELISA
EBV: VCA IgM Ab.	Serum, heparin plasma, EDTA plasma, citrated plasma	ELISA

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Analyte (measurement parameter)	Test material (matrix)	Test technique
HBe antigen	Serum, lithium heparin plasma, sodium heparin plasma, EDTA plasma	CLIA
Hepatitis A Ab.	Serum, lithium heparin plasma, sodium heparin plasma, EDTA plasma	CLIA
Hepatitis A IgM	Serum, lithium heparin plasma, sodium heparin plasma, EDTA plasma	CLIA
Hepatitis B HBsAg confirmatory test	Serum, lithium heparin plasma, sodium heparin plasma, EDTA plasma	CLIA
Hepatitis B HBc Ab.	Serum, EDTA-Plasma	CLIA
Hepatitis B HBc IgM	Serum, lithium heparin plasma, sodium heparin plasma, EDTA plasma	CLIA
Hepatitis B HBe Ab.	Serum, lithium heparin plasma, sodium heparin plasma, EDTA plasma	CLIA
Hepatitis B HBsAg	Serum, lithium heparin plasma, sodium heparin plasma, EDTA plasma	CLIA
Hepatitis B HBs Ab.	Serum, lithium heparin plasma, sodium heparin plasma, EDTA plasma	CLIA
Hepatitis C Ab.	Serum, lithium heparin plasma, sodium heparin plasma, EDTA plasma	CLIA
Hepatitis C	Serum, EDTA-Plasma	recombinant immunoblot
Hepatitis D Ab.	Serum, sodium citrate plasma, EDTA plasma, heparin plasma, sodium fluoride / potassium oxalate plasma	CLIA
HIV (1/2- Ab., p24 Ag)	Serum, EDTA-Plasma	CLIA
HSV 1/2-IgG Ab.	CSF, serum	ELISA
Measles IgG/IgM Ab.	Serum, heparin plasma, EDTA plasma, citrated plasma	ELISA
Measles IgG Ab.	CSF, serum	ELISA
Mumps IgG/IgM Ab.	Serum, heparin plasma, EDTA plasma, citrated plasma	ELISA

Analyte (measurement parameter)	Test material (matrix)	Test technique
Parvovirus B19 IgG/IgM Ab.	Serum, heparin plasma, EDTA plasma, citrated plasma	ELISA
Rotavirus AG	Stool	ELISA
Rubella IgG/IgM Ab.	Serum, heparin plasma, EDTA plasma	CLIA
VZV IgG/IgA/IgM Ab.	Serum, heparin plasma, EDTA plasma, citrated plasma	ELISA
VZV IgG Ab.	CSF, serum	ELISA

Type of examination:
Molecular biological examinations (amplification methods)*

Analyte (measurement parameter)	Test material (matrix)	Test technique
CMV-DNA qualitative	EDTA blood, sputum, urine, CSF	Nucleic acid amplification with parallel detection of amplicons via probe hybridization
EBV DNA qualitative	EDTA blood, CSF, BAL, saliva	Nucleic acid amplification with parallel detection of amplicons via probe hybridization
Enteroviruses	Cerebral spinal fluid (CSF)	Nucleic acid amplification with parallel detection of amplicons via probe hybridization
Gastro-Virus Multiplex Norovirus I+II, Adeno-, Rota-, Astro-, Sapovirus	Stool	Nucleic acid amplification with parallel detection of amplicons via probe hybridization
HBV DNA qualitative and quantitative	EDTA plasma, citrated plasma, serum	Nucleic acid amplification with parallel detection of amplicons via probe hybridization
HBV DNA quantitative	EDTA plasma, citrated plasma, serum	Nucleic acid amplification with parallel detection of amplicons via TaqMan probe hybridization
HCV RNA qualitative	EDTA plasma, citrated plasma, serum	Nucleic acid amplification with parallel detection of amplicons via TaqMan probe hybridization
HCV RNA qualitative & quantitative	EDTA plasma, citrated plasma, serum	Nucleic acid amplification with parallel detection of amplicons via TaqMan probe hybridization
HCV genotyping	EDTA plasma, citrated plasma, serum	Nested-PCR+ Sanger sequencing Seq. in 5'NCR

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Analyte (measurement parameter)	Test material (matrix)	Test technique
HIV-1 resistance determination, genotypic	EDTA plasma	Nested PCR Sanger sequencing
HIV-1 RNA qualitative & quantitative	EDTA plasma, citrated plasma,	Nucleic acid amplification with parallel detection of amplicons via TaqMan probe hybridization
HIV-1/HIV-2 RNA qualitative	EDTA plasma, serum	Real-Time PCR = Nucleic acid amplification with parallel detection of amplicons via TaqMan probe hybridization
HIV-1/HIV-2 RNA qualitative	EDTA plasma, serum	Real-Time PCR = Nucleic acid amplification with parallel detection of amplicons via TaqMan probe hybridization
HSV DNA qualitative	CSF, smear	Nucleic acid amplification with parallel detection of amplicons via probe hybridization
HSV / VZV	Smears, liquor	Real-Time PCR = Nucleic acid amplification with parallel detection of amplicons via TaqMan probe hybridization
Human Papilloma Virus	Smears	Nucleic acid amplification with parallel detection of amplicons via probe hybridization
Influenza A/B & RSV	Swab, BAL, tracheal secretion	Nucleic acid amplification with parallel detection of amplicons via probe hybridization
Influenza A+B RSV	Smears, BAL, tracheal secretion	Nucleic acid amplification with parallel detection of amplicons via TaqMan probe hybridization
Norovirus	Stool	Nucleic acid amplification with parallel detection of amplicons via TaqMan probe hybridization
Parvovirus B19 DNA qualitative/quantitative	EDTA plasma, citrated plasma, serum	Nucleic acid amplification with parallel detection of amplicons via probe hybridization
SARS-CoV-2 /Coronavirus qualitative	Smears, BAL, tracheal secretion, throat rinse water	Real-Time PCR = Nucleic acid amplification with parallel detection of amplicons via TaqMan probe hybridization

Analyte (measurement parameter)	Test material (matrix)	Test technique
VZV-DNA qualitative	CSF, smear	Nucleic acid amplification with parallel detection of amplicons via probe hybridization

Medical laboratory fields: Transfusion medicine

Type of examination:
Agglutination tests*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Antibody differentiation	Native whole blood, EDTA whole blood	Gel centrifugation method
direct Coombs test	Native whole blood, EDTA whole blood	Gel centrifugation method
indirect Coombs test	Native whole blood, EDTA whole blood	Gel centrifugation method, manual procedure
Blood group determinationABO-System	Native whole blood, EDTA whole blood	Gel centrifugation method
Rh formula	Native whole blood, EDTA whole blood	Gel centrifugation method
Kell antigen	Native whole blood, EDTA whole blood	Gel centrifugation method
Search for irregular antibodies	Native whole blood, EDTA whole blood	Gel centrifugation method, manual procedure