

Deutsche Akkreditierungsstelle

Annex to the Accreditation Certificate D-ML-21356-01-00 according to DIN EN ISO 15189:2014

Valid from: 06.07.2023

Date of issue: 06.07.2023

Holder of accreditation certificate:

MVZ Martinsried GmbH

Zentrum für Humangenetik und Laboratoriumsdiagnostik (MVZ)

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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, cytogenetics)

Microbiology

Virology

Transfusion medicine

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 <http://www.dakks.de>.

Continuation on next site

Annex to the accreditation certificate D-ML-21356-01-00

Continuation:

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 test methods are exemplary. The medical laboratory maintains a current list of all test methods in a flexible scope of accreditation.

The medical laboratory maintains a current list of all test methods in a flexible scope of accreditation.

Medical laboratory field: Clinical chemistry

Type of examination:

Flow cytometry (including blood cell counting)*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Complete blood count (CBC)	EDTA blood	Particle count, particle size determination, determination of cytochemical-cytometric characteristics
CBC with differentiation	EDTA blood	Particle count, particle size determination, determination of cytochemical-cytometric characteristics
Reticulocytes	EDTA blood	Determination of cytochemical-cytometric characteristics

Type of examination:

Electrophoresis*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Monoclonal gammopathy	Serum	Capillary electrophoresis
Serum protein	Serum	Capillary electrophoresis

Type of examination:

Electrochemical tests*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Chloride	Serum, urine	ISE
Potassium	Serum, urine	ISE
Sodium	Serum, urine	ISE

Type of examination:

Coagulometry*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Antithrombin III	Citrate plasma	Optical detection methods
D-dimer	Citrate plasma	Optical detection methods
Fibrinogen	Citrate plasma	Optical detection methods
INR	Citrate plasma	Optical detection methods
Partial thromboplastin time	Citrate plasma	Optical detection methods
Thromboplastin time	Citrate plasma	Optical detection methods

Type of examination:

Ligand assays*

Analyte (measurement parameter)	Test material (matrix)	Test technique
AFP	Amniotic fluid	Immunometry (CLIA)
AFP	Serum	ECLIA
Beta hCG	Serum	ECLIA
CA 125	Serum	ECLIA
CA 15-3	Serum	ECLIA
CA 19-9	Serum	ECLIA
CEA	Serum	ECLIA
Cortisol	Serum	ECLIA
DHEA-S	Serum	ECLIA
Folic acid	Serum	ECLIA
Free beta hCG	Serum	Immunometry (CLIA)
FSH	Serum	ECLIA
FT3	Serum	ECLIA
FT4	Serum	ECLIA
LH	Serum	ECLIA
Estradiol	Serum	ECLIA
PAPP-A	Serum	Immunometry (CLIA)
Progesterone	Serum	ECLIA
Prolactin	Serum	ECLIA
PSA	Serum	ECLIA
SHBG	Serum	ECLIA
Testosterone	Serum	ECLIA
Troponin T	Serum	ECLIA
TSH	Serum	ECLIA
Vitamin B12	Serum	ECLIA
Vitamin D	Serum	ECLIA
Factor 13	Citratplasma	Turbidimetric immunoassay
von Willebrand-factor antigen	Citratplasma	Turbidimetric immunoassay
von Willebrand-factor activity	Citratplasma	Turbidimetric immunoassay
Calprotectin	Stuhl	ELISA
17-OH-Progesterone	Serum	ELISA
Aldosterone	Serum	Immunometry (CLIA)

Type of examination:
Microscopy*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Atypical lymphocytes	Whole blood	Bright field microscopy after staining with dyes
Basophilic granulocytes	Whole blood	Bright field microscopy after staining with dyes
Blasts	Whole blood	Bright field microscopy after staining with dyes
Eosinophilic granulocytes	Whole blood	Bright field microscopy after staining with dyes
Smudge cells	Whole blood	Bright field microscopy after staining with dyes
Lymphocytes	Whole blood	Bright field microscopy after staining with dyes
Metamyelocytes	Whole blood	Bright field microscopy after staining with dyes
Monocytes	Whole blood	Bright field microscopy after staining with dyes
Erythrocyte morphology	Whole blood	Bright field microscopy after staining with dyes
Leukocyte morphology	Whole blood	Bright field microscopy after staining with dyes
Thrombocyte morphology	Whole blood	Bright field microscopy after staining with dyes
Myelocytes	Whole blood	Bright field microscopy after staining with dyes
Normoblasts	Whole blood	Bright field microscopy after staining with dyes
Plasma cells	Whole blood	Bright field microscopy after staining with dyes
Promyelocytes	Whole blood	Bright field microscopy after staining with dyes
Segmented neutrophil	Whole blood	Bright field microscopy after staining with dyes
Band neutrophil	Whole blood	Bright field microscopy after staining with dyes
Erythrocytes	Urine, urine sediment	Bright field microscopy
Red blood cell casts	Urine, urine sediment	Bright field microscopy
Granular casts	Urine, urine sediment	Bright field microscopy
Hyaline casts	Urine, urine sediment	Bright field microscopy
Leukocytes	Urine, urine sediment	Bright field microscopy
Leukocyte casts	Urine, urine sediment	Bright field microscopy
Squamous epithelial cells	Urine, urine sediment	Bright field microscopy

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Analyte (measurement parameter)	Test material (matrix)	Test technique
Round epithelial cells	Urine, urine sediment	Bright field microscopy
Transitional epithelial cells	Urine, urine sediment	Bright field microscopy
Waxy casts	Urine, urine sediment	Bright field microscopy

Type of examination:

Qualitative test (simple) with visual check*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Bilirubin	Urine	Test strips
Glucose	Urine	Test strips
Hemoglobin/erythrocytes	Urine	Test strips
Ketone	Urine	Test strips
Leukocytes	Urine	Test strips
Nitrite	Urine	Test strips
pH	Urine	Test strips
Protein	Urine	Test strips
Urobilinogen	Urine	Test strips

Type of examination:

Spectrometry (turbidimetry)*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Alpha-1 antitrypsin	Serum	Turbidimetry
C-reactive protein	Serum	Turbidimetry
Ceruloplasmin	Serum	Turbidimetry
Ferritin	Serum	Turbidimetry
Haptoglobin	Serum	Turbidimetry
HbA1c	EDTA blood	Turbidimetry
Transferrin	Serum	Turbidimetry

Type of examination:

Spectrometry (photometry)*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Albumin	Serum	UV-/VIS-Photometry
Alkaline phosphatase	Serum	UV-/VIS-Photometry
Amylase	Serum	UV-/VIS-Photometry
Bilirubin, direct	Serum	UV-/VIS-Photometry
Bilirubin, total	Serum	UV-/VIS-Photometry
Calcium	Serum	UV-/VIS-Photometry
Cholinesterase	Serum	UV-/VIS-Photometry
Cholesterol	Serum	UV-/VIS-Photometry
Creatine kinase (CK)	Serum	UV-/VIS-Photometry

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Analyte (measurement parameter)	Test material (matrix)	Test technique
CK-MB	Serum	UV-/VIS-Photometry
Iron	Serum	UV-/VIS-Photometry
Protein, total	Serum	UV-/VIS-Photometry
Protein	Urine	UV-/VIS-Photometry
GGT	Serum	UV-/VIS-Photometry
GOT (AST)	Serum	UV-/VIS-Photometry
GPT (ALT)	Serum	UV-/VIS-Photometry
Glucose	Serum, NaF plasma	UV-/VIS-Photometry
Uric acid	Serum	UV-/VIS-Photometry
Urea	Serum	UV-/VIS-Photometry
HDL cholesterol	Serum	UV-/VIS-Photometry
Creatinine	Serum	UV-/VIS-Photometry
LDH	Serum	UV-/VIS-Photometry
LDL	Serum	UV-/VIS-Photometry
Lipase	Serum	UV-/VIS-Photometry
Magnesium	Serum	UV-/VIS-Photometry
Phosphate	Serum	UV-/VIS-Photometry
Triglycerides	Serum	UV-/VIS-Photometry
Blood sedimentation	EDTA blood	Stopped flow technique

Type of examination:

Osmometry

Analyt (Messgröße)	Untersuchungsmaterial (Matrix)	Untersuchungstechnik
Osmolality	Serum, urine	cryoscopy

Medical laboratory field: Immunology

Type of examination:

Flow cytometry**

Analyte (measurement parameter)	Test material (matrix)	Test technique
Lymphocyte typing	CPDA1 blood, EDTA blood	Flow cytometry

Type of examination:

Ligand assays*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Anti-liver kidney microsomal antibodies (LKM-1)	Serum, EDTA, heparin or citrate plasma	Immunoblot (test strips)
Antimitochondrial antibodies against pyruvate dehydrogenase complex (AMA-M2)	Serum, EDTA, heparin or citrate plasma	Immunoblot (test strips)
Liver cytosolic antigen type 1 (LC-1)	Serum, EDTA, heparin or citrate plasma	Immunoblot (test strips)
Soluble liver antigen/liver pancreas antigen (SLA/LP)	Serum, EDTA, heparin or citrate plasma	Immunoblot (test strips)
MAK	Serum	ECLIA
TAK	Serum	ECLIA
Fusion protein of the E2 subunits of the inner mitochondrial membrane alpha-keto acid dehydrogenases (M2-3E(BPO))	Serum, EDTA, heparin or citrate plasma	Immunoblot (test strips)

Type of examination:

Microscopy*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Antinuclear antibodies (ANA)	Whole blood, serum, plasma	Indirect immunofluorescence microscopy
Antimitochondrial antibodies (AMA)	Whole blood, serum, plasma	Indirect immunofluorescence microscopy
Antineutrophil cytoplasmic antibodies (ANCA)	Whole blood, serum, plasma	Indirect immunofluorescence microscopy
Anti-smooth muscle antibodies (ASMA)	Whole blood, serum, plasma	Indirect immunofluorescence microscopy
Anti-liver kidney microsomal antibodies (LKM-1)	Whole blood, serum, plasma	Indirect immunofluorescence microscopy

Type of examination:

Spectrometry (turbidimetry)*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Ig A	Serum	Turbidimetry
Ig G	Serum	Turbidimetry
IgM	Serum	Turbidimetry
Rheumatoid factor	Serum	Turbidimetry

Medical laboratory field: Human genetics (cytogenetics)

Type of examination:

Chromosome analysis**

Analyte (measurement parameter)	Test material (matrix)	Test technique
Innate chromosome set	Peripheral blood, amniotic fluid, chorionic villi and other tissue samples ^a , umbilical cord blood, bone marrow	Chromosome band analysis, fluorescence in situ hybridization (FISH): Prenatal rapid test, microdeletion diagnostics, chromosome painting, subtelomere analysis, interphase studies, multicolor karyotyping
Acquired chromosome set (tumor cytogenetics)	Blood, bone marrow	Chromosome band analysis, fluorescence in situ hybridization (FISH)
Innate chromosome set	Blood, native and cultured cells from amniotic fluid, chorionic villi and other tissue samples ^a ; DNA	Array based CGH
Innate chromosome set	Blood, cultured cells from amniotic fluid or chorionic villi; DNA	Molecular karyotyping

^a The samples are processed and analyzed by the laboratory without prior histological evaluation.

Medical laboratory field: Human genetics (molecular human genetics)

Type of examination:

Molecular biological tests (amplification and hybridization procedures)**

Indication and analyte (gene(s), variant(s))	Test material (matrix)	Test technique
Drug intolerance (CYP2C19)	EDTA blood, DNA; DNA	Fluorescence-labeled hybridization probes
Thrombophilia (F2, F5)	EDTA blood, DNA; DNA	Fluorescence-labeled hybridization probes
Segregation analysis, CNV confirmation/exclusion, STRC-CNV analysis (genomic imbalances)	EDTA blood, DNA, tissue samples ^a , cultured cells from amniotic fluid and chorionic villi; DNA	Fluorescence-labeled hybridization probes
Somatic variants in solid tumors (KRAS)	EDTA blood, EDTA bone marrow, lithium-heparin blood, lithium-heparin bone marrow, BCT blood, DNA; DNA	Fluorescence-labeled hybridization probes

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Indication and analyte (gene(s), variant(s))	Test material (matrix)	Test technique
AML (AML-ETO fusion gene)	EDTA blood, EDTA bone marrow, lithium-heparin blood, lithium-heparin bone marrow, RNA, cDNA; RNA, cDNA	Fluorescence-labeled hybridization probes
Chimerism (chimerism analysis)	EDTA blood, EDTA bone marrow, lithium-heparin blood, lithium-heparin bone marrow, DNA; DNA	Fluorescence-labeled hybridization probes
Osteogenesis imperfecta (OI) (BMP1, COL1A1, COL1A2, CRTAP, FKBP10, IFITM5, LEPRE1, NR5A1, P3H1, PLOD2, PPIB, PSMC3IP, SERPINF1, SERPINH1, SP7, TMEM38B, WNT1)	EDTA blood, DNA; DNA	Sequence capture (TWIST), Sequencing-by synthesis, Dragen, VarSeq (Golden Helix)
Metabolic myopathies (glycogenoses with muscular symptoms and cartinine metabolism disorders) (ACADVL, AGK, ALDOA, CPT2, GAA, LDHA, NOTCH2, PFKM, PGAM2, PHKA1, PHKB, PYGM, SALL4, SLC25A20, TBX3, TBX5)	EDTA blood, DNA; DNA	Sequence capture (TWIST), Sequencing-by synthesis, Dragen, VarSeq (Golden Helix)
Myeloid neoplasms (ABL1, ANKRD26, ASXL1, ASXL2, BCOR, BCORL1, BRAF, CALR, CBL, CD177, CDKN2A, CEBPA, CSF3R, CUX1, DDX41, DHX15, DNMT1, DNMT3A, DNMT3B, ELANE, ETNK1, ETV6, EZH2, FLT3, GATA1, GATA2, GNAS, IDH1, IDH2, IKZF1, JAK1, JAK2, JAK3, KDM6A, KIT, KMT2A, KRAS, MAG, MAP2K1, MECOM, MPL, MYC, NF1, NOTCH1, NPM1, NRAS, PDGFRA, PDGFRB, PHF6, PRPF8, PTEN, PTPN11, RAD21, RB1, RUNX1, SCRIB, SETBP1, SF3B1, SH2B3, SMC1A, SMC3, SRSF2, STAG2, STAT5B, TET1, TET2, TP53, U2AF1, WT1, ZBTB7A, ZRSR2)	EDTA blood, DNA; DNA	Sequence capture (TWIST), Sequencing-by synthesis, Dragen, VarSeq (Golden Helix); Amplicon-based NGS, Sequencing-by synthesis, JSI medical systems SeqNext

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Indication and analyte (gene(s), variant(s))	Test material (matrix)	Test technique
Fusions in solid tumors (NTRK3-ETV6, EWSR1-NR4A3, EWSR1-PBX1, EWSR1-ZNF384, EWSR1-ATF1, EWSR1-PATZ1, EWSR1-DDIT3, EWSR1-SP3, EWSR1-FEV, EWSR1-CREB1, EWSR1-FLI1, EWSR1-ETV4, EWSR1-ETV1, EWSR1-ERG, YY1-EWSR1, EWSR1-ZNF444, EWSR1-SMARCA5, NFATC2-EWSR1, SS18-SSX1, SS18-SSX4, FUS-CREB3L2, FUS-CREB3L1, FUS-DDIT3, FUS-ERG, FUS-ATF1, FUS-FEV)	DNA, RNA, cDNA; RNA, cDNA	Ampliseq, NGS semiconductor sequencing, Ion PGM System, IonReporter
Fusion in leukemias/lymphomas (ACTN4-MLL, BCR-ABL1, CBFB-MYH11, CDK6-MLL, DEK-CAN, DEK-NUP214, ETV6-ABL1, ETV6-MECOM, ETV6-PDGFRB, ETV6-RUNX1, FUS-ERG, LASP1-MLL, LPP-MLL, MAPRE1-MLL, MLL-ABI1, MLL-ABI2, MLL-ACACA, MLL-ACTN4, MLL-AFF1, MLL-AFF3, MLL-AFF4, MLL-ARHGAP26, MLL-ARHGEF12, MLL-CASC5, MLL-CASP8AP2, MLL-CBL, MLL-CENPK, MLL-CEP170B, MLL-CREBBP, MLL-CT45A2, MLL-DAB2IP, MLL-DCPS, MLL-EEFSEC, MLL-ELL, MLL-EP300, MLL-EPS15, MLL-FLNA, MLL-FOXO3, MLL-FRYL, MLL-GAS7, MLL-GMPS, MLL-GPHN, MLL-KIAA1524, MLL-LASP1, MLL-LPP, MLL-MAML2, MLL-MLLT1, MLL-MLLT10, MLL-MLLT11, MLL-MLLT3, MLL-MLLT4, MLL-MLLT6, MLL-MYO1F, MLL-NCKIPSD, MLL-NRIP3, MLL-PDS5A, MLL-PICALM, MLL-SEPT11, MLL-SEPT2, MLL-SEPT5, MLL-SEPT6, MLL-SEPT9, MLL-SH3GL1, MLL-SORBS2, MLL-TET1, MLL-TOP3A, MLL-ZFYVE19, MN1-ETV6, NPM1-ALK, NPM1-MLF1, NPM1-RARA, NUP98-MLL, PAX5-PML, PML-RARA, RPN1-MECOM, continuation next line	EDTA blood, EDTA bone marrow, lithium-heparin blood, lithium-heparin bone marrow, RNA, bone marrow, cDNA; RNA, cDNA	Ampliseq, NGS semiconductor sequencing, Ion PGM System, IonReporter
Continuation: RUNX1-MECOM, RUNX1-RUNX1T1, SET-NUP214, STILTAL1, TCF3-HLF, TCF3-PBX1)	EDTA blood, EDTA bone marrow, lithium-heparin blood, lithium-heparin bone marrow, RNA, bone marrow, cDNA; RNA, cDNA	Ampliseq, NGS semiconductor sequencing, Ion PGM System, IonReporter

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Indication and analyte (gene(s), variant(s))	Test material (matrix)	Test technique
Lynch syndrome (HNPCC) (MLH1, MSH2 , MSH6 , PMS2, EPCAM)	EDTA blood, DNA; DNA	PCR, Sanger sequencing, NGS (semiconductor sequencing, Ion PGM System Thermofisher)
Oncomine Focus (HotSpots: AKT1, ALK, AR, BRAF, CDK4, CTNNB1, DDR2, EGFR, ERBB2, ERBB3, ERBB4, ESR1, FGFR2, FGFR3, GNA11, GNAQ, HRAS, IDH1, IDH2, JAK1, JAK2, JAK3, KIT, KRAS, MAP2K1, MAP2K2, MET, MTOR, NRAS, PDGFRA, PIK3CA, RAF1, RET, ROS1, SMO, CNV: ALK, AR, BRAF, CCND1, CDK4, CDK6, EGFR,ERBB2, FGFR1, FGFR2, FGFR3, FGFR4, KIT, KRAS, MET, MYC, MYCN, PDGFRA, PIK3CA, Fusionen: ABL1, AKT3, ALK, AXL, BRAF, EGFR, ERBB2, ERG, ETV1, ETV4, ETV5, FGFR1, FGFR2, FGFR3, MET, NTRK1, NTRK2, NTRK3, PDGFRA, PPARG, RAF1, RET, ROS1)	DNA, RNA, cDNA; DNA, RNA, cDNA	Ampliseq, NGS semiconductor sequencing, Ion PGM-System, IonReporter; Sequencing-by synthesis, Dragen, VarSeq (Golden Helix)
Somatic variants in breast cancer(cfBreast- (AKT1, EGFR, ERBB2, ERBB3, ESR1, FBXW7, KRAS, PIK3CA, SF3B1, TP53))	BCT blood, DNA; cfDNA	Ampliseq, NGS semiconductor sequencing, Ion PGM-System, IonReporter
Prader-Willi syndrome (PWS) (SNRPN)	EDTA blood, DNA; DNA	(MS) MLPA

Type of examination:

Molecular biological tests (amplification procedures)**

Indication and analyte (gene(s), variant(s))	Test material (matrix)	Test technique
Azoospermia (AZF microdeletion)	EDTA blood, DNA; DNA	Fragment Length analysis
Macular degeneration, age-related (ARMD4) (CFH-Gen)	EDTA blood, DNA; DNA	Fragment Length analysis
Pancreatitis, hereditary (CPA1, CTRC, PRSS1, SPINK1)	EDTA blood, DNA; DNA	Fragment Length analysis
Muscular atrophy, spinobulbar (SBMA, Kennedy's disease) (AR gene)	EDTA blood, DNA; DNA	Fragment Length analysis
Solid tumors (microsatellite instability)	DNA; DNA	Fragment Length analysis
Ataxias, spinocerebellar autosomal dominant (SCA1) (ATXN1 gene)	EDTA blood, DNA; DNA	Fragment Length analysis

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Indication and analyte (gene(s), variant(s))	Test material (matrix)	Test technique
Ataxia, Friedreich (FRDA1) (FXN gene)	EDTA blood, DNA; DNA	Fragment Length analysis
PGT-M (diagnostic at high risk of a serious monogenic hereditary disease)	Trophoectodermal cells in the context of PID and/or polar body in the context of PBD; DNA	NGS (Sequencing-by-synthesis) after Whole genome amplification (WGA, Sureplex DNA Amplification System), Bluefuse Multi Software
Uniparental disomy 14/15 (UPD 14/15)	Genomic DNA; DNA	Fragment Length analysis
Aneuploidy diagnostics (non-invasive prenatal test, NIPT): trisomy 21, trisomy, 18, trisomy 13, gonosomal aberrations	BCT blood (Streck), cell free (fetal & maternal) DNA; DNA	Whole genome sequencing, sequencing by synthesis, Dragen
PGT-A (Aneuploidy diagnostics), chromosome set (to clarify a de novo chromosome change)	Trophoectodermal cells in the context of PID and/or polar body in the context of PBD, genomic DNA from single cells; DNA	NGS (Sequencing-by-synthesis) after Whole genome amplification (WGA, Sureplex DNA Amplification System), Bluefuse Multi Software
PGT-SR (Translocation diagnostics), Partial chromosome set (to clarify a known familial chromosome change)	Trophoectodermal cells in the context of PID and/or polar body in the context of PBD, genomic DNA from single cells; DNA	NGS (Sequencing-by-synthesis) after Whole genome amplification (WGA, Sureplex DNA Amplification System), Bluefuse Multi Software
Short Tandem Repeats-/ Microsatellite analysis	Genomic DNA; DNA	Fragment Length analysis
Whole Exome Sequencing	Genomic DNA; DNA	Sequence capture, Sequencing-by-synthesis, Bioinformaticpipeline, VarSeq (Golden Helix)
Hearing loss, autosomal recessive, nonsyndromic (GJB2, GJB6 genes)	EDTA blood, DNA; DNA	(MS) MLPA
PGT-A, PGT-SR	genomic DNA from single cells, polar bodies, Trophoectodermal cells; DNA	WGA, Sequencing-by-synthesis

Type of examination:

Molecular biological tests (hybridization procedures)**

Indication and analyte (gene(s), variant(s))	Test material (matrix)	Test technique
Fragile X syndrome (FMR1 gene)	EDTA blood, DNA; DNA	Southern blot hybridization

Medical laboratory field: Microbiology

Type of examination:

Agglutination tests*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Streptococci	Bacterial culture	Particle agglutination
Treponema pallidum antibodies	Serum, EDTA plasma	Particle agglutination

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Analyte (measurement parameter)	Test material (matrix)	Test technique
Treponema pallidum infection associated, non-specific lipoid antibodies (IgG, IgM)	Serum, EDTA plasma	Particle agglutination

Type of examination:
Bacterial susceptibility testing*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Bacteria	Germ colonies in pure culture	Agar diffusion test, partial broth dilution method as minimum inhibitory concentration (MIC) with extrapolation

Type of examination:
Microbial differentiation/identification/typing*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Bacteria	Germ colonies in pure culture	Biochemical, orientating
Bacteria	Isolated bacteria	Biochemical, complex
Yeasts	Isolated fungi	Biochemical, complex

Type of examination:
Culture examinations*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Bacteria, fungi	Swab (urogenital, ENT), blood, skin, wound, punctate, stool	In CO ₂ atmosphere, microaerobic/anaerobic atmosphere, specific, unspecific
Bacteria, fungi	Urine	Specific, unspecific, inhibition test, cell count

Type of examination:
Ligand assays*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Diphtheria toxoid, IgG	Serum, EDTA plasma	ELISA
Borrelia burgdorferi sensu lato IgG, IgM	Serum, EDTA plasma	CLIA
Borrelia burgdorferi sensu lato IgG, IgM	Serum, EDTA plasma	Immunoblot
Clostridium difficile toxin A/B antig.	Stool	ELISA

Type of examination:

Microscopy*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Bacteria, fungi	Swab	Bright field microscopy after staining with dyes
Bacteria	Urine, urine sediment	Bright field microscopy
Fungi	Urine, urine sediment	Bright field microscopy

Type of examination:

Molecular biological tests (amplification procedures)*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Bordetella pertussis, DNA	Swab, sputum	Real-time PCR
Borrelia burgdorferi, DNA	DNA, punctate, cerebrospinal fluid	Real-time PCR
Chlamydia trachomatis, Neisseria gonorrhoeae, DNA	Swab, urine, ejaculate	Real-time PCR (duplex PCR, oligoplex PCR)

Medical laboratory field: Virology

Type of examination:

Ligand assays*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Cytomegalovirus, IgG, IgM	Serum, EDTA plasma	ELISA
Hepatitis A virus, Ig	Serum, EDTA plasma	CMIA
Hepatitis C virus, Ig	Serum, EDTA plasma	Immunoblot
SARS-CoV-2 IgG	Serum, EDTA plasma	ECLIA

Type of examination:

Molecular biological tests (amplification procedures)*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Influenza viruses, respiratory syncytial virus	Swab, sputum	Real-time PCR (Oligoplex-PCR)
Hepatitis B virus, DNA, quantitative	Serum, EDTA plasma	Real-time PCR
Parvovirus B19 DNA	Biopsy material, EDTA plasma	Real-time PCR
SARS-CoV-2	Swab, throat rinse	Real-time PCR

Type of examination:

Molecular biological tests (amplification procedures)**

Analyte (measurement parameter)	Test material (matrix)	Test technique
Hepatitis C virus, RNA, genotype core	Serum, EDTA plasma	Real-time PCR

Medical laboratory field: Transfusion medicine

Type of examination:

Agglutination tests**

Analyte (measurement parameter)	Test material (matrix)	Test technique
ABO blood group typing	EDTA blood/whole blood	Hemagglutination test/gel technique
Serum cross matching for ABO typing	EDTA blood/whole blood	Hemagglutination test/gel technique
Rh-D typing	EDTA blood/whole blood	Hemagglutination test/gel technique
Rhesus type	EDTA blood/whole blood	Hemagglutination test/gel technique
Kell antigen system	EDTA blood/whole blood	Hemagglutination test/gel technique
Antiglobulin test	EDTA blood/whole blood	Hemagglutination test/gel technique
Direct Coombs test	EDTA blood/whole blood	Hemagglutination test/gel technique

Type of examination:

Flow cytometry**

Analyte (measurement parameter)	Test material (matrix)	Test technique
HLA crossmatch	CPDA1 blood, serum	Flow cytometry
HLA antibody	Serum	Solid phase assay

Type of examination:

Molecular biological tests (amplification procedures)*

Analyte (measurement parameter)	Test material (matrix)	Test technique
HLA class I, II	Genomic DNA	PCR-SSO
HLA class I, II	Genomic DNA	PCR-SSP
HLA class I, II	Genomic DNA	DNA sequencing
HLA class I, II	Genomic DNA	Sequencing-by synthesis, MiSeq/NovaSeq Illumina, IMGT HLA data base
HLA class I, II	Genomic DNA	Sequencing-by synthesis, MiSeq, IMGT HLA data base
KIR	Genomic DNA	PCR-SSP
KIR	Genomic DNA	PCR-SSO
Detection of exons 5, 7 and 10 of the RHD gene	fetal cfDNA from maternal plasma (EDTA)	Real-time PCR