

Deutsche Akkreditierungsstelle GmbH

Annex to the Accreditation Certificate D-ML-13280-01-00 according to DIN EN ISO 15189:2014

Period of validity: 14.02.2018 to 13.02.2023

Date of issue: 06.12.2018

Holder of certificate:

AescuLabor Hamburg GmbH
Haferweg 36, 22769 Hamburg

Examinations in the field:

Medical laboratory diagnostics

Medical laboratory fields:

Clinical Chemistry

Immunology

Human genetics (molecular human genetics)

Microbiology

Transfusion medicine/Immunoematology

Virology

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

Within the given examination field 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.

Medical laboratory field: Clinical chemistry

Type of examination:

Aggregometry

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

Type of examination:

Chromatography (liquid chromatography-mass spectrometry (LC-MS))**

Analyte (measurement parameter)	Test material (matrix)	Test technique
10-OH carbamazepine	Serum, plasma	LC-MS/MS
Amiodarone	Serum, plasma	LC-MS/MS
Amisulpride	Serum, plasma	LC-MS/MS
Amitriptyline	Serum, plasma	LC-MS/MS
Carnitine	Ejaculate	LC-MS/MS
Citalopram	Serum, plasma	LC-MS/MS
Clomipramine	Serum, plasma	LC-MS/MS
Clozapine	Serum, plasma	LC-MS/MS
Cortisol	Urine	LC-MS/MS
Cyclosporine A	EDTA blood	LC-MS/MS
Desethylamiodarone	Serum, plasma	LC-MS/MS
Desipramine	Serum, plasma	LC-MS/MS
Doxepine	Serum, plasma	LC-MS/MS
Escitalopram	Serum, plasma	LC-MS/MS
Estrone	Serum, plasma	LC-MS/MS
Ethosuximide	Serum, plasma	LC-MS/MS
Everolimus	EDTA blood	LC-MS/MS
Flecainide	Serum, plasma	LC-MS/MS
Flupenthixol	Serum, plasma	LC-MS/MS
Fluphenazine	Serum, plasma	LC-MS/MS
Gabapentin	Serum, plasma	LC-MS/MS
Haloperidol	Serum, plasma	LC-MS/MS
Imipramine	Serum, plasma	LC-MS/MS
Lamotrigine	Serum, plasma	LC-MS/MS
Levetiracetam	Serum, plasma	LC-MS/MS
Maprotiline	Serum, plasma	LC-MS/MS
Metanephrine	Plasma	LC-MS/MS
Methylmalonic acid	Serum, plasma	LC-MS/MS
Mirtazapine	Serum, plasma	LC-MS/MS
Mycophenolic acid	Serum, plasma	LC-MS/MS
Norclomipramine	Serum, plasma	LC-MS/MS
Norclozapine	Serum, plasma	LC-MS/MS
Nordoxepine	Serum, plasma	LC-MS/MS
Normetanephrine	Plasma	LC-MS/MS
Nortriptyline	Serum, plasma	LC-MS/MS
Oxcarbazepine	Serum, plasma	LC-MS/MS

Analyte (measurement parameter)	Test material (matrix)	Test technique
Paliperidone	Serum, plasma	LC-MS/MS
Paroxetine	Serum, plasma	LC-MS/MS
Perphenazine	Serum, plasma	LC-MS/MS
Phenytoin	Serum, plasma	LC-MS/MS
Pregabalin	Serum, plasma	LC-MS/MS
Primidone	Serum, plasma	LC-MS/MS
Promethazine	Serum, plasma	LC-MS/MS
Risperidone	Serum, plasma	LC-MS/MS
Sertraline	Serum, plasma	LC-MS/MS
Sirolimus	EDTA blood	LC-MS/MS
Sultiame	Serum, plasma	LC-MS/MS
Tacrolimus (FK506)	EDTA blood	LC-MS/MS
Topiramate	Serum, plasma	LC-MS/MS
Trimipramine	Serum, plasma	LC-MS/MS
Venlafaxine	Serum, plasma	LC-MS/MS
Zonisamide	Serum, plasma	LC-MS/MS

Type of examination:

Chromatography (high performance liquid chromatography (HPLC))*

Analyte (measurement parameter)	Test material (matrix)	Test technique
5-Hydroxyindoleacetic acid	Urine	HPLC-ECD
Adrenaline	Plasma, urine	HPLC-ECD
Beta-carotene	Serum, plasma	HPLC-UV detection
Dopamine	Plasma, urine	HPLC-ECD
Haemoglobin separation	EDTA blood	HPLC
HbA1c	EDTA blood	HPLC
Homocysteine	Serum, plasma	HPLC-fluorescence detection
Homovanillic acid	Urine	HPLC-ECD
Metanephrine	Urine	HPLC-ECD
Noradrenaline	Plasma, urine	HPLC-ECD
Normetanephrine	Urine	HPLC-ECD
Serotonin	Serum, urine	HPLC-ECD
Vanillylmandelic acid	Urine	HPLC-ECD
Vitamin A	Serum, plasma	HPLC-UV detection
Vitamin B1	EDTA blood	HPLC-fluorescence detection
Vitamin B2	EDTA blood	HPLC-fluorescence detection
Vitamin B6	EDTA plasma	HPLC-fluorescence detection
Vitamin C	Lithium heparin plasma, serum	HPLC-UV detection
Vitamin E	Serum, plasma	HPLC-UV detection

Type of examination:

Flow cytometry (including blood cell counting)*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Basophils	EDTA	Flow cytometry
Eosinophils	EDTA	Flow cytometry
Erythrocytes	EDTA	Flow cytometry
Haematocrit	EDTA	Flow cytometry
Leukocytes	EDTA	Flow cytometry
Lymphocytes	EDTA	Flow cytometry

Analyte (measurement parameter)	Test material (matrix)	Test technique
MCH	EDTA	Flow cytometry
MCHC	EDTA	Flow cytometry
MCV	EDTA	Flow cytometry
Monocytes	EDTA	Flow cytometry
Neutrophils	EDTA	Flow cytometry
NRBC	EDTA	Flow cytometry
Reticulocytes	EDTA	Flow cytometry
Reticulocytes Hb	EDTA	Flow cytometry
Platelets	EDTA, citrate blood	Flow cytometry

Type of examination:

Electrochemical tests (potentiometry)*

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

Type of examination:

Electrophoresis*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Albumin	Serum	Capillary electrophoresis
CK-isoenzymes	Serum	Agarose gel electrophoresis
Urine protein separation	Urine	SDS-agarose gel electrophoresis
Immune fixation	Serum, urine	Immunofixation electrophoresis
Serum electrophoresis	Serum	Capillary electrophoresis

Type of examination:

Coagulometry* (optical detection method)

Analyte (measurement parameter)	Test material (matrix)	Test technique
Activated partial thromboplastin time	Citrated plasma	Coagulometry
APC resistance	Citrated plasma	Coagulometry
Dabigatran	Citrated plasma	Coagulometry
Factor II activity	Citrated plasma	Coagulometry
Factor IX activity	Citrated plasma	Coagulometry
Factor V activity	Citrated plasma	Coagulometry
Factor VII activity	Citrated plasma	Coagulometry
Factor VIII activity	Citrated plasma	Coagulometry
Factor X activity	Citrated plasma	Coagulometry
Factor XI activity	Citrated plasma	Coagulometry
Factor XII activity	Citrated plasma	Coagulometry
Fibrinogen	Citrated plasma	Coagulometry
Calculated fibrinogen	Citrated plasma	Coagulometry
Lupus anticoagulant (DRVVT)	Citrated plasma	Coagulometry
Lupus anticoagulant (sens. aPTT)	Citrated plasma	Coagulometry
Quick (prothrombin time)	Citrated plasma	Coagulometry
Thrombin time	Citrated plasma	Coagulometry

Type of examination:

Ligand assays*

Analyte (measurement parameter)	Test material (matrix)	Test technique
25-hydroxy vitamin D (vit. D3)	Serum	ECLIA
ACTH	EDTA plasma	ECLIA
AFP	Serum	ECLIA
TPO mAb	Serum	ECLIA
Amphetamine screening	Urine	EIA
Anti-CCP	Serum	ECLIA
Antithrombin immunological	Citrated plasma	Immunodiffusion
Barbiturate screening	Urine	EIA
Benzodiazep. screening	Urine	EIA
Beta-2-glycoprotein IgG Ab	Citrate plasma, serum	CLIA
Beta-2-glycoprotein IgM Ab	Citrate plasma, serum	CLIA
CA 125	Serum	ECLIA
CA 15-3	Serum	ECLIA
CA 19-9	Serum	ECLIA
CA 72-4	Serum	ECLIA
Calprotectin	Stool	EIA
Cannabis screening	Urine	EIA
Carbamazepine	Serum	EIA
Cardiolipin-IgG Ab	Citrate plasma, serum	CLIA
Cardiolipin-IgM Ab	Citrate plasma, serum	CLIA
CEA	Serum	ECLIA
Cortisol	Serum	ECLIA
C-peptide	Serum	ECLIA
Cyfra 21-1	Serum	ECLIA
DHEA-S	Serum	ECLIA
Diamine oxidase	Serum	ELISA
Digitoxin	Serum	ECLIA
Digoxin	Serum	ECLIA
Factor VIII antigen	Citrated plasma	ELISA
Ferritin	Serum	ECLIA
Fibrinogen immunological	Citrated plasma	Immunodiffusion
Folic acid	Serum	ECLIA
Free T3	Serum	ECLIA
Free T4	Serum	ECLIA
FSH	Serum	ECLIA
Human sex hormone binding	Serum	ECLIA
IgE	Serum	ECLIA
Insulin	Serum	ECLIA
LH	Serum	ECLIA
Methadone screening	Urine	EIA
Methadone metabolite	Urine	EIA
Myoglobin	Serum	ECLIA
NSE	Serum	ECLIA
NT-pro-BNP	Serum	ECLIA

Analyte (measurement parameter)	Test material (matrix)	Test technique
Oestradiol	Serum	ECLIA
Opiates screening	Urine	EIA
Pancreatic elastase	Stool	EIA
PIGF	Serum	ECLIA
Procalcitonin (PCT)	Serum	ECLIA
Progesterone	Serum	ECLIA
Prolactin	Serum	ECLIA
Protein Z	Citrated plasma	ELISA
PSA	Serum	ECLIA
PSA, free	Serum	ECLIA
PTH intact	EDTA plasma	ECLIA
sFlt-1	Serum	ECLIA
Beta-HCG	Serum	ECLIA
Testosterone	Serum	ECLIA
Theophylline	Serum	KIMS
Thyroglobulin Ab (TgAb)	Serum	ECLIA
Troponin T HS	Serum	ECLIA
TSH	Serum	ECLIA
TSH receptor Ab (TSHRab)	Serum	ECLIA
Tumour marker S100	Serum	ECLIA
Valproic acid	Serum	EIA
Vancomycin	Serum	EIA
Vitamin B12	Serum	ECLIA
VWF collagen binding capacity	Citrated plasma	ELISA

Type of examination:

Microscopy*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Differential blood count	EDTA	Bright-field microscopy

Type of examination:

Spectrometry (atom absorption spectrometry (AAS))**

Analyte (measurement parameter)	Test material (matrix)	Test technique
Aluminium	Serum, plasma	AAS
Copper	Serum, plasma	AAS
Selenium	Serum, plasma	AAS
Zinc	Serum, plasma, ejaculate	AAS

Type of examination:

Spectrometry (ICP-MS)**

Analyte (measurement parameter)	Test material (matrix)	Test technique
Iodine	Urine, serum, plasma	ICP-MS
Selenium	Serum, plasma	ICP-MS

Type of examination:

Spectrometry (UV/VIS photometry)*

Analyte (measurement parameter)	Test material (matrix)	Test technique
ACE	Serum	Photometry
Albumin	Serum	Photometry
Alkaline phosphatase	Serum	Photometry
Alpha-amylase	Serum	Photometry
Alpha-glucosidase	Ejaculate	Photometry
Amylase	Urine	Photometry
Anti Xa units	Citrated plasma	VIS photometry
Antithrombin activity	Citrated plasma	VIS photometry
Bilirubin (neonatal)	Serum	Photometry
Bilirubin total	Serum	Photometry
Bilirubin conjugated	Serum	Photometry
Erythrocyte sedimentation rate	EDTA blood	Photometry
Calcium	Serum	Photometry
Calcium	Urine	Photometry
CHE	Serum	Photometry
Cholesterol	Serum	Photometry
CK total	Serum	Photometry
CK-MB	Serum	Photometry
Iron	Serum	Photometry
Protein	Urine	Photometry
Ethanol	Serum	Photometry
Fructosamine	Serum	Photometry
Fructose	Ejaculate	Photometry
Bile acids	Serum	Photometry
Total protein	Serum	Photometry
GLDH	Serum	Photometry
Glucose	Serum	Photometry
Glucose	Citrated fluoride plasma, NaF	Photometry
Glucose	Urine	Photometry
Glucose	Haemolysate	Photometry
GOT	Serum	Photometry
GPT	Serum	Photometry
Haemoglobin	EDTA	Photometry
Haemoglobin	EDTA	Photometry
Uric acid	Serum	Photometry
Uric acid	Urine	Photometry
Urea	Serum	Photometry
Urea	Urine	Photometry
HDL cholesterol	Serum	Photometry
LDL cholesterol calculated		Calculation
Cocaine metab. screening	Urine	Photometry
Creatinine	Serum	Photometry
Creatinine	Urine	Photometry
Creatinine clearance	Serum, urine	Calculation

Analyte (measurement parameter)	Test material (matrix)	Test technique
LDH	Serum	Photometry
LDL cholesterol	Serum	Photometry
Lipase	Serum	Photometry
Lithium	Serum	Photometry
Magnesium	Serum	Photometry
Phosphate, inorganic	Serum	Photometry
Phosphate, inorganic	Urine	Photometry
Plasminogen	Citrated plasma	VIS photometry
Protein C activity	Citrated plasma	VIS photometry
Rivaroxaban	Citrated plasma	VIS photometry
Acid phosphatase	Serum	Photometry
Triglycerides	Serum	Photometry
Y-GT	Serum	Photometry
Citric acid	Ejaculate	Photometry

Type of examination:

Spectrometry (turbidimetry/immunoturbidimetry)*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Albumin	Urine	Immunoturbidimetry
Alpha-1-antitrypsin	Serum	Immunoturbidimetry
Apolipoprotein A	Serum	Immunoturbidimetry
Apolipoprotein B	Serum	Immunoturbidimetry
ASL	Serum	Immunoturbidimetry
Beta-2 microglobulin	Serum	Immunoturbidimetry
Caeruloplasmin	Serum	Immunoturbidimetry
C-reactive protein	Serum	Immunoturbidimetry
C-reactive protein hs	Serum	Immunoturbidimetry
Cystatin C	Serum	Immunoturbidimetry
D-dimers	Citrated plasma	Immunoturbidimetry
Factor XIII antigen	Citrated plasma	Immunoturbidimetry
Free kappa light chains	Serum, urine	Immunoturbidimetry
Free lambda light chains	Serum, urine	Immunoturbidimetry
Haptoglobin	Serum	Immunoturbidimetry
IgA	Serum	Immunoturbidimetry
IgG	Serum	Immunoturbidimetry
IgG subclass 1	Serum	Immunoturbidimetry
IgG subclass 2	Serum	Immunoturbidimetry
IgG subclass 3	Serum	Immunoturbidimetry
IgG subclass 4	Serum	Immunoturbidimetry
IgM	Serum	Immunoturbidimetry
Complement C3	Serum	Immunoturbidimetry
Complement C4	Serum	Immunoturbidimetry
Lipoprotein A	Serum	Immunoturbidimetry
Occult blood	Stool	Immunoturbidimetry
Protein S free	Citrated plasma	Immunoturbidimetry
Rheumatoid factor	Serum	Immunoturbidimetry
Transferrin	Serum	Immunoturbidimetry
Transferrin saturation		Calculation
Von Willebrand factor activity	Citrated plasma	Immunoturbidimetry
Von Willebrand factor antigen	Citrated plasma	Immunoturbidimetry

Type of examination:

Spectrometry (reflectometry /carrier test methods)*

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

Medical Laboratory field: Immunology

Type of examination:

Flow cytometry (including blood cell counting)*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Activated monocytes (HLA-DR+)	EDTA blood	Immunophenotyping
Activated NK cells	EDTA blood	Immunophenotyping
B-lymphocyte differentiation	EDTA blood	Immunophenotyping
B-cell subpopulations	EDTA blood	Immunophenotyping
Granulocyte function test	Heparin blood	Cell migration test
Granulocyte function test	Heparin blood	Oxidative burst
Lymphocyte differentiation	EDTA blood	Immunophenotyping
Regulatory T-lymphocytes	EDTA blood	Immunophenotyping
T-lymphocyte differentiation	EDTA blood	Immunophenotyping

Type of examination:

Ligand assays*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Actin Ab	Serum, plasma	ELISA
AMA-M2	Serum, plasma	ELISA
AMA-M2 liver-specific Ab	Serum, plasma	Immunoblot
CENP (centromeres) Ab	Serum, plasma	FEIA
CENP-A Ab	Serum, plasma	Immunoblot
CENP-B Ab	Serum, plasma	Immunoblot
CH 100	Serum, plasma	RID
CTD Ab	Serum, plasma	FEIA
DNS Ab	Serum, plasma	FEIA
dsDNS Ab	Serum, plasma	Immunoblot
ECP	Serum, plasma	FEIA
Fibrillarin Ab	Serum, plasma	Immunoblot
GAD Ab	Serum, plasma	ELISA
GBM Ab	Serum, plasma	FEIA
Gliadin IgA Ab	Serum, plasma	FEIA
Gliadin IgG Ab	Serum, plasma	FEIA
GP210 Ab	Serum, plasma	Immunoblot
Histones Ab	Serum, plasma	Immunoblot
Jo-1 Ab	Serum, plasma	FEIA
Jo-1 Ab	Serum, plasma	Euroline
Ku Ab	Serum, plasma	Immunoblot
Ku Ab	Serum, plasma	Immunoblot

Analyte (measurement parameter)	Test material (matrix)	Test technique
LC1	Serum, plasma	Immunoblot
LKM1 Ab	Serum, plasma	Immunoblot
M2-3E (BPO)	Serum, plasma	Immunoblot
Gastric parietal cells Ab	Serum, plasma	ELISA
Mi-2 Ab	Serum, plasma	Immunoblot
MPO Ab	Serum, plasma	FEIA
NOR90 Ab	Serum, plasma	Immunoblot
PCNA Ab	Serum, plasma	Immunoblot
PDGFR Ab	Serum, plasma	Immunoblot
PL-12 Ab	Serum, plasma	Immunoblot
PL-7 Ab	Serum, plasma	Immunoblot
PM/Scl 100 Ab	Serum, plasma	Immunoblot
PM/Scl 75 Ab	Serum, plasma	Immunoblot
PML	Serum, plasma	Immunoblot
PM-Scl Ab	Serum, plasma	Immunoblot
Proteinase 3 / PR3	Serum, plasma	FEIA
Rheumatoid factor IgA / IgM	Serum, plasma	FEIA
Rib-P Ab	Serum, plasma	FEIA
RNA polymerase III 11 Ab	Serum, plasma	Immunoblot
RNA polymerase III 155 Ab	Serum, plasma	Immunoblot
Ro-52 Ab	Serum, plasma	Immunoblot
Scl-70 Ab	Serum, plasma	FEIA
Scl-70 Ab	Serum, plasma	Immunoblot
SLA Ab	Serum, plasma	Immunoblot
Sm Ab	Serum, plasma	FEIA
SP100 Ab	Serum, plasma	Immunoblot
Specific IgE	Serum, plasma	FEIA
SS-A (Ro) Ab	Serum, plasma	FEIA
SS-B (La) Ab	Serum, plasma	FEIA
Systemic sclerosis profile Ab	Serum, plasma	Immunoblot
Th/To Ab	Serum, plasma	Immunoblot
Tyrosin phosphatase (IA2) Ab	Serum, plasma	ELISA
Tryptase	Serum, plasma	FEIA
U1-RNP Ab	Serum, plasma	FEIA

Type of examination:

Microscopy*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Actin Ab	Serum	Immunofluorescence microscopy
AMA	Serum	Immunofluorescence microscopy
ANA	Serum	Immunofluorescence microscopy
cANCA	Serum	Immunofluorescence microscopy
Crithidia Ab	Serum	Immunofluorescence microscopy
Islet cell (ICA) Ab	Serum	Immunofluorescence microscopy
LKM Ab	Serum	Immunofluorescence microscopy
Adrenal cortex Ab	Serum	Immunofluorescence microscopy
pANCA	Serum	Immunofluorescence microscopy
SMA	Serum	Immunofluorescence microscopy
xANCA	Serum	Immunofluorescence microscopy

Medical laboratory field: Human genetics (molecular human genetics)

Type of examination:

Molecular biological tests (amplification procedures)**

Analyte (measurement parameter)	Test material (matrix)	Test technique
Factor II prothrombin mutation 20210	EDTA blood	Fluorescence-labelled hybridisation probes
Factor V Leiden mutation 1691	EDTA blood	Fluorescence-labelled hybridisation probes
Haemochromatosis	EDTA blood	Fluorescence-labelled hybridisation probes
Hereditary fructose intolerance HFI	EDTA blood	Analysis of amplification products by gel electrophoresis and sequencing
HLA-B 27	EDTA blood	Melting point analysis of amplification products with intercalating stain
Lactose intolerance mutation 13910	EDTA blood	Fluorescence-labelled hybridisation probes
MHTFR mutation 677	EDTA blood	Fluorescence-labelled hybridisation probes
Plasminogen activator inhibitor-1 mutation PAI	EDTA blood	Fluorescence-labelled hybridisation probes

Medical laboratory field: Microbiology

Type of examination:

Agglutination tests*

Analyte (measurement parameter)	Test material (matrix)	Test technique
ASTA (antistaphylolysin reaction)	Serum	Latex particle agglutination
Cardiolipin flocculation test (VDRL)	Serum	Carbon microparticle agglutination
E. coli K1 antigen test	Culture material	Latex agglutination
EPEC (dyspepsia coli)	Culture material	Object carrier agglutination
Meningitis pathogens (N. meningitidis A, B, C, Y, W135, Haemophilus influenzae type B, Streptococcus pneumoniae, Streptococcus group B, E. coli K1)	Cerebrospinal fluid	Latex agglutination
MRSA (detection of PBP2a)	Culture material	Latex agglutination
Pneumococci	Culture material	Latex agglutination
Salmonella serotyping	Culture material	Object carrier agglutination
Shigella differentiation	Culture material	Object carrier agglutination
Streptococci differentiation	Culture material	Latex agglutination
TPPA (Treponema pallidum)	Serum	Passive particle agglutination
Yersinia serotyping	Culture material	Object carrier agglutination

Type of examination:

Bacterial and fungal susceptibility tests*

Analyte (measurement parameter)	Test material (matrix)	Test technique
PBP 2a test	Suspect MRSA culture isolates	Latex agglutination
Resistance determination of aerobic and anaerobic bacteria, yeasts	Culture isolates	MIC determination by Etest (epsilometry)
Resistance determination of fast-growing aerobic bacteria	Culture isolates	Broth microdilution method, break point, fully mechanised, agar dilution test, photometry, partially mechanised
Resistance determination of fast-growing aerobic bacteria; ESBL confirmatory test	Culture isolates	Agar diffusion test
Beta-lactamase testing of aerobic and anaerobic bacteria	Culture isolates	Cefinase test

Type of examination:

Microbial differentiation/identification/typing*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Aerobic and anaerobic bacteria	Culture material	Biochemical, mass spectrometric pathogen differentiation
Yeasts	Culture material	Biochemical, mass spectrometric pathogen differentiation
Arcobacter	Culture material	Biochemical
Campylobacter spp.	Culture material	Biochemical, mass spectrometric pathogen differentiation
Gardnerella vaginalis	Culture material	Biochemical, mass spectrometric pathogen differentiation
Helicobacter pylori	Culture material	Biochemical, mass spectrometric pathogen differentiation

Type of examination:

Culture examinations*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Aerobic enteropathogenic bacteria; as applicable Bacillus cereus, Clostridium difficile, Clostridium perfringens, Staphylococcus aureus, fungi	Stool	Non-specific and specific culture methods, in aerobic, microaerophilic and where applicable anaerobic atmosphere
Aerobic (entero)pathogenic bacteria, Neisseria gonorrhoeae	Anal, rectal swab	Non-specific and specific culture methods, in aerobic, microaerophilic atmosphere
Aerobic bacteria, yeasts	Urine dip slides	Non-specific culture methods, in aerobic atmosphere
Aerobic bacteria, yeasts; as applicable mycoplasmas and ureaplasmas	Midstream, catheter and bladder puncture urine	Non-specific and specific culture methods, in aerobic (possibly microaerophilic) atmosphere, inhibitor detection, concentration determination in surface plating technique
Aerobic bacteria, fungi	Swabs from the upper respiratory tract, ear canal swabs, conjunctival swabs, respiratory secretions (sputum, tracheal, bronchial secretions, BAL), skin swabs	Non-specific and specific culture methods, in aerobic and microaerophilic atmosphere
Aerobic enteropathogenic bacteria	Intestinal biopsy	Non-specific and specific culture methods, in aerobic, microaerophilic atmosphere

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Analyte (measurement parameter)	Test material (matrix)	Test technique
Aerobic and anaerobic bacteria	IUD, IUD swab	Non-specific and specific culture methods, in aerobic, microaerophilic and anaerobic atmosphere
Aerobic and anaerobic bacteria in general and specifically: Gardnerella vaginalis, Haemophilus spp., Listeria monocytogenes, Neisseria gonorrhoeae, mycoplasmas, ureaplasmas; yeasts	Swabs from the genital tract, ejaculate, abscess swabs and aspirates from the urogenital area, amniotic fluid	Non-specific and specific culture methods, in aerobic, microaerophilic and anaerobic atmosphere
Aerobic and anaerobic bacteria, fungi	Tissue / biopsy material	Non-specific culture methods, in aerobic, microaerophilic and anaerobic atmosphere
Aerobic and anaerobic bacteria, fungi	Catheter tips: Venous (peripheral and central), arterial, drainage, tracheal and bladder catheters	Non-specific and specific culture methods, in aerobic, microaerophilic and anaerobic atmosphere
Aerobic and anaerobic bacteria, fungi	Blood and aspirates in blood culture medium	Non-specific culture method, fluorometry, fully automated
Aerobic and anaerobic bacteria, fungi, actinomycetes	Wound swab, abscess swab, maxillary sinus swab, gingiva swab, umbilical swab, abscess material, pleural aspirate, various aspirates	Non-specific and specific culture methods, in aerobic, microaerophilic and anaerobic atmosphere
Aerobic and anaerobic bacteria, fungi	Cerebrospinal fluid	Non-specific and specific culture methods, in aerobic, microaerophilic and anaerobic atmosphere
Actinomycetes	Abscess or empyema pus, biopsy material, bronchial secretions, gland, fistula secretions, IUD	Specific culture method in anaerobic atmosphere
Corynebacterium diphtheriae	Throat swab, tonsil swab	Specific culture method
Dermatophytes	Nail parings, dandruff, hair, swabs	Specific culture method in aerobic atmosphere
Enterobacteriaceae, ESBL-producing organisms, MRGN	Primary sterile human material, respiratory material, swabs, urine, stool	Non-specific culture method in aerobic atmosphere combined with agar diffusion, microdilution or Etest
Yeasts	Nail parings, dandruff, hair, swabs	Specific culture method in aerobic atmosphere
Helicobacter pylori	Gastric biopsy, duodenal biopsy	Specific culture method, in microaerophilic atmosphere
Moulds	Nail parings, dandruff, hair, swabs	Specific culture method in aerobic atmosphere

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Analyte (measurement parameter)	Test material (matrix)	Test technique
Staphylococcus aureus, MRSA	Primary sterile human material, respiratory material, swabs, urine, stool	Specific culture method in aerobic atmosphere combined with sensitivity testing (microdilution, PBP2a)
Vancomycin-resistant enterococci (VRE)	Primary sterile human material, respiratory material, swabs, urine, stool	Specific culture method in aerobic atmosphere combined with microdilution, Etest)
Vibrio cholerae	Stool, rectal swab, vomit	Specific culture method, in aerobic atmosphere

Type of examination:
Ligand assays*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Bordetella pertussis IgA Ab	Serum	ELISA
Bordetella pertussis IgG Ab	Serum	ELISA
Bordetella pertussis IgM Ab	Serum	ELISA
Borrelia burgdorferi IgG blot	Serum	Western blot
Borrelia burgdorferi IgM blot	Serum	Western blot
Borrelia burgdorferi screening procedure IgG Ab	Serum	ELISA
Borrelia burgdorferi screening procedure IgM Ab	Serum	ELISA
Campylobacter jejuni IgG Ab	Serum	ELISA
Campylobacter jejuni IgA Ab	Serum	ELISA
Chlamydia pneumoniae IgG Ab	Serum	ELISA
Chlamydia pneumoniae IgM Ab	Serum	ELISA
Chlamydia trachomatis IgG Ab	Serum	ELISA
Chlamydia trachomatis IgM Ab	Serum	ELISA
Clostridium difficile GDH antigen	Stool	EIA
Clostridium difficile toxin A/B	Stool	EIA
Cryptosporidium antigen	Stool	EIA
Diphtheria toxin IgG Ab	Serum	ELISA
E. coli Shiga (vero)toxin I and II	Culture isolates, stool	EIA
Entamoeba histolytica antigen	Stool	EIA
Giardia lamblia antigen	Stool	EIA
Helicobacter pylori IgA Ab	Serum	ELISA
Helicobacter pylori IgA blot	Serum	Western blot
Helicobacter pylori IgG Ab	Serum	ELISA
Helicobacter pylori IgG blot	Serum	Western blot
Mycoplasma pneumoniae IgA Ab	Serum	ELISA
Mycoplasma pneumoniae IgG Ab	Serum	ELISA
Mycoplasma pneumoniae IgM Ab	Serum	ELISA
Quantiferon	Blood	ELISA
Tetanus toxin IgG Ab	Serum	ELISA

Analyte (measurement parameter)	Test material (matrix)	Test technique
Toxoplasma gondii IgG avidity	Serum	ELFA
Toxoplasma gondii IgG Ab	Serum	CMIA
Toxoplasma gondii IgG Ab	Serum	ELFA
Toxoplasma gondii IgM Ab	Serum	CMIA
Treponema pallidum Ab	Serum	CMIA
Treponema pallidum IgG blot	Serum	Immunoblot
Treponema pallidum IgM blot	Serum	Immunoblot
Yersinia IgA blot	Serum	Immunoblot
Yersinia IgG Ab	Serum	ELISA
Yersinia IgG blot	Serum	Immunoblot
Yersinia IgA Ab	Serum	ELISA

Type of examination:

Microscopy*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Amoebas	Stool	Bright-field microscopy after enrichment, Lugol
Bacteria, fungi	Swabs, secretions, aspirates, pus, tissue, urine, cerebrospinal fluid, blood culture, culture material	Bright-field microscopy after staining (Gram staining)
Corynebacterium diphtheriae	Culture material	Bright-field microscopy after staining (Neisser)
Dermatophytes	Skin, hair, nails	KOH preparation
Ectoparasites	Ectoparasites	Bright-field microscopy without staining
Giardia lamblia	Stool	Bright-field microscopy after enrichment, Lugol
Helminth identification	Helminths	Direct or bright-field microscopy without staining
Coccidia	Stool	Bright-field microscopy after staining (Kinyoun)
Plasmodium spec. (direct malaria detection in thick drops and blood swab)	EDTA blood, capillary blood	Bright-field microscopy after staining (Giemsa, Pappenheim)
Mycoplasmas, ureaplasmas	Culture plates	Bright-field microscopy without staining
Oxyurids eggs	Anal contact preparation	Bright-field microscopy without staining
Moulds, dermatophytes	Culture material	Bright-field microscopy without staining or after lactophenol blue staining
Schistosoma eggs	Urine	Bright-field microscopy after enrichment, without staining
Worm eggs, protozoa cysts	Stool	Bright-field microscopy after enrichment

Type of examination:

Molecular biological tests (amplification procedures)**

Analyte (measurement parameter)	Test material (matrix)	Test technique
Atopobium vaginae	Genito-anal swab	Fluorescence-labelled hybridisation probes
Bak 16S mRNA	Culture, EDTA blood, serum, cerebrospinal fluid	Fluorescence-labelled hybridisation probes
Bordetella parapertussis	Nasopharyngeal swabs, BAL sputum, pharyngeal lavage	Fluorescence-labelled hybridisation probes
Bordetella pertussis DNA	Nasopharyngeal swabs, BAL sputum, pharyngeal lavage	Fluorescence-labelled hybridisation probes
Campylobacter	Stool samples	Fluorescence-labelled hybridisation probes
Candida spez./Aspergillus	EDTA, cerebrospinal fluid, BAL, biopsy specimens, aspirates	Fluorescence-labelled hybridisation probes
Chlamydia pneumoniae DNA	Nasopharyngeal swabs, BAL sputum, pharyngeal lavage	Fluorescence-labelled hybridisation probes
Chlamydia trachomatis DNA	Swabs (conjunctival, genital, anal), BAL sputum	Fluorescence-labelled hybridisation probes
Clostridium difficile	Stool samples	Fluorescence-labelled hybridisation probes
Cryptosporidium	Stool samples	Fluorescence-labelled hybridisation probes
Dientamoeba/ Entamoeba histolytica	Stool samples	Fluorescence-labelled hybridisation probes
Enterogaagregative E. coli	Stool samples	Fluorescence-labelled hybridisation probes
Enterohemorrhagic E. coli	Stool samples	Fluorescence-labelled hybridisation probes
Enteroinvasive E. coli	Stool samples	Fluorescence-labelled hybridisation probes
Enteropathogenic E. coli	Stool samples	Fluorescence-labelled hybridisation probes
Enterotoxigenic E. coli	Stool samples	Fluorescence-labelled hybridisation probes
Gardnerella vaginalis	Genito-anal swab	Fluorescence-labelled hybridisation probes
Giardia lamblia	Stool samples	Fluorescence-labelled hybridisation probes
Haemophilus influenza	Nasopharyngeal swabs, BAL, sputum	Fluorescence-labelled hybridisation probes
Klebsiella pneumoniae	Respiratory material, cerebrospinal fluid, urine, blur	Fluorescence-labelled hybridisation probes
Legionella pneumophila DNA	Nasopharyngeal swabs, BAL, sputum, pharyngeal lavage	Fluorescence-labelled hybridisation probes

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Analyte (measurement parameter)	Test material (matrix)	Test technique
Moraxella catharralis	Nasopharyngeal swabs, BAL, sputum	Fluorescence-labelled hybridisation probes
MRSA DNA	Nasopharyngeal swabs, BAL sputum, pharyngeal lavage, wound swabs	Fluorescence-labelled hybridisation probes
Mycoplasma genitalium	Urogenital and cervical swabs, urine	Fluorescence-labelled hybridisation probes
Mycoplasma hominis	Genito-anal swabs, urine	Fluorescence-labelled hybridisation probes
Mycoplasma pneumoniae DNA	Nasopharyngeal swabs, BAL sputum, pharyngeal lavage	Fluorescence-labelled hybridisation probes
Neisseria gonorrhoeae DNA	Genital swabs	Fluorescence-labelled hybridisation probes
Pseudomonas aeruginosa	Swab, BAL, sputum, biopsy specimen aspirates, EDTA blood, cerebrospinal fluid	Fluorescence-labelled hybridisation probes
Salmonella enteritis	Stool samples	Fluorescence-labelled hybridisation probes
Staphylococcus aureus	Swabs (nasopharyngeal), BAL, sputum	Fluorescence-labelled hybridisation probes
Streptococcus pneumoniae	Nasopharyngeal swabs, BAL, sputum, pharyngeal lavage	Fluorescence-labelled hybridisation probes
Streptococcus pyogenes	Nasopharyngeal swabs, BAL, sputum, pharyngeal lavage	Fluorescence-labelled hybridisation probes
Toxoplasma gondii	Serum, EDTA, cerebrospinal fluid, BAL, sputum, biopsy specimens, aspirates, amniotic fluid	Fluorescence-labelled hybridisation probes
Treponema pallidum	Swab of primary effect (Ulcus durum)	Fluorescence-labelled hybridisation probes
Trichomonas vaginalis	Urogenital and urethral swabs, ejaculate	Fluorescence-labelled hybridisation probes
Tropheryma whipplei	Cerebrospinal fluid, biopsy specimens	Fluorescence-labelled hybridisation probes
Ureaplasma urealyticum	Urogenital and vaginal swabs, tracheal secretions	Fluorescence-labelled hybridisation probes
Vibrio cholerae	Stool samples	Fluorescence-labelled hybridisation probes
Yersinia	Stool samples	Fluorescence-labelled hybridisation probes

Medical laboratory field: Transfusion medicine/immunohaematology

Type of examination:

Agglutination tests*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Antibody differentiation, titer determination	EDTA blood, whole blood	Indirect agglutination tests
Blood group, Rhesus factor Antibody test	EDTA blood, whole blood	Direct agglutination
Direct Coombs test	EDTA blood	Direct anti-human globulin test

Medical laboratory field: Virology

Type of examination:

Ligand assays*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Adenovirus antigen	Stool	EIA
CMV avidity	Serum	ELFA
CMV IgG Ab	Serum	ECLIA
CMV IgG Ab	Serum	ELFA
CMV IgM Ab	Serum	ECLIA
CMV IgM Ab	Serum	ELFA
EBNA IgG Ab	Serum	ELISA
EBV IgG Ab	Serum	ELISA
EBV IgM Ab	Serum	ELISA
Enteroviruses IgG Ab	Serum	ELISA
Enteroviruses IgM Ab	Serum	ELISA
HCV blot	Serum	Immunoblot
Hep B anti HBc IgG Ab	Serum	ECLIA
Hep B anti HBc IgM Ab	Serum	ECLIA
Hep B anti-HBs Ab	Serum	ECLIA
Hep B Bs Ag	Serum	ECLIA
Hep B HBe Ag	Serum	ECLIA
Hep B HBe Ab	Serum	ECLIA
Hep Bs Ag confirmatory test	Serum	ECLIA
Hepatitis A IgG Ab	Serum	ECLIA
Hepatitis A IgM Ab	Serum	ECLIA
Hepatitis C Ab	Serum	ECLIA
HIV 1/2 screening procedure	Serum	ECLIA
HIV confirmatory test	Serum	ELFA
HIV blot	Serum	Immunoblot
HSV IgG Ab	Serum	ELISA
HSV IgM Ab	Serum	ELISA
Measles IgG Ab	Serum	ELISA
Measles IgM Ab	Serum	ELISA
Mumps IgG Ab	Serum	ELISA
Mumps IgM Ab	Serum	ELISA
Parvovirus IgG Ab	Serum	ELISA
Parvovirus IgM Ab	Serum	ELISA
Rotavirus antigen	Stool	EIA
Rubella IgG Ab	Serum	ECLIA
Rubella IgM Ab	Serum	ECLIA
VZV IgA Ab	Serum	ELISA
VZV IgG Ab	Serum	ELISA
VZV IgG Ab	Serum	ELFA
VZV IgM Ab	Serum	ELISA

Type of examination:

Molecular biological tests (amplification procedures)**

Analyte (measurement parameter)	Test material (matrix)	Test technique
Adenovirus DNA and typing	Serum, EDTA blood, cerebrospinal fluid, swabs, BAL, sputum, biopsy specimens, aspirates, stool, urine	Fluorescence-labelled hybridisation probes
Astrovirus RNA	Stool samples	Fluorescence-labelled hybridisation probes
BK virus DNA	EDTA blood, cerebrospinal fluid, aspirates, urine, serum	Fluorescence-labelled hybridisation probes
Bocavirus DNA	Nasopharyngeal swabs, BAL sputum, pharyngeal lavage	Fluorescence-labelled hybridisation probes
Coronavirus RNA	Nasopharyngeal swabs, BAL sputum, pharyngeal lavage	Fluorescence-labelled hybridisation probes
Cytomegalovirus (CMV) DNA	Serum, EDTA blood, cerebrospinal fluid, swabs, BAL, sputum, biopsy specimens, aspirates, stool, urine	Fluorescence-labelled hybridisation probes
Enterovirus RNA	EDTA blood, cerebrospinal fluid, swabs, aspirates, stool	Fluorescence-labelled hybridisation probes
Epstein-Barr virus (EBV) DNA	EDTA blood, cerebrospinal fluid, BAL sputum, biopsy specimens, aspirates	Fluorescence-labelled hybridisation probes
Hepatitis B resistance and typing DNA	EDTA blood, serum	Analysis of amplification products by gel electrophoresis and sequencing
Hepatitis C virus genotyping RNA	Serum, EDTA blood	Analysis of amplification products by gel electrophoresis and sequencing
Hepatitis E virus RNA	Stool samples, biopsy specimens	Fluorescence-labelled hybridisation probes
Herpes simplex virus (HSV) DNA and typing	Serum, EDTA blood, cerebrospinal fluid, swabs, BAL sputum, aspirates	Fluorescence-labelled hybridisation probes
HIV integrase inhibitor resistance	Serum, EDTA plasma	Analysis of amplification products by gel electrophoresis and sequencing
HIV coreceptor usage	Serum, EDTA plasma	Analysis of amplification products by gel electrophoresis and sequencing
HIV resistance and typing DNA	EDTA blood	Analysis of amplification products by gel electrophoresis and sequencing

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Analyte (measurement parameter)	Test material (matrix)	Test technique
Human herpes viruses type 6 DNA	Serum, EDTA blood, cerebrospinal fluid	Fluorescence-labelled hybridisation probes
Human metapneumovirus (hMPV) RNA	Nasopharyngeal swabs, BAL sputum, pharyngeal lavage	Fluorescence-labelled hybridisation probes
Human papillomavirus (HPV) DNA	Genito-anal swabs, biopsy specimens	Analysis of amplification products by gel electrophoresis and sequencing
Influenza swH1N1 virus RNA	Nasopharyngeal swabs, BAL sputum, pharyngeal lavage	Fluorescence-labelled hybridisation probes
Influenza virus A/B RNA and typing	Nasopharyngeal swabs, BAL sputum, pharyngeal lavage	Fluorescence-labelled hybridisation probes
Measles virus RNA	Serum, EDTA, cerebrospinal fluid, mucosal swab	Fluorescence-labelled hybridisation probes
MERS coronavirus RNA	Pharyngeal lavage, BAL, tracheal secretions, nasopharyngeal swab	Fluorescence-labelled hybridisation probes
Mumps virus RNA	Serum, EDTA, cerebrospinal fluid, swabs	Fluorescence-labelled hybridisation probes
Norovirus RNA	Stool samples	Fluorescence-labelled hybridisation probes
Parainfluenza virus 1,2,3,4 RNA	Nasopharyngeal swabs, BAL sputum, pharyngeal lavage	Fluorescence-labelled hybridisation probes
Parechovirus RNA	Cerebrospinal fluid, swabs, aspirates, EDTA blood, stool	Fluorescence-labelled hybridisation probes
Parvovirus B 19 DNA	Amniotic fluid, EDTA blood, cerebrospinal fluid, biopsy specimens, aspirates	Fluorescence-labelled hybridisation probes
Rhinovirus RNA	Nasopharyngeal swabs, BAL sputum, pharyngeal lavage	Fluorescence-labelled hybridisation probes
Rubella virus RNA	Serum, EDTA, cerebrospinal fluid	Fluorescence-labelled hybridisation probes
RS virus RNA	Nasopharyngeal swabs, BAL sputum, pharyngeal lavage	Fluorescence-labelled hybridisation probes
Sapovirus RNA	Stool samples	Fluorescence-labelled hybridisation probes
Varicella zoster virus DNA	Serum, EDTA blood, cerebrospinal fluid, swabs, BAL sputum, aspirates	Fluorescence-labelled hybridisation probes