

Deutsche Akkreditierungsstelle GmbH

Annex to the Accreditation Certificate D-ML-13413-01-00 according to DIN EN ISO 15189:2014

Valid from: 24.02.2022

Date of issue: 24.02.2022

Holder of certificate:

Medizinisches Versorgungszentrum SYNLAB Leverkusen GmbH
Paracelsusstr. 13, 51375 Leverkusen

Examinations in the field:

Medical Laboratory Diagnostics

Medical laboratory fields:

Clinical chemistry

Immunology

Human genetics (molecular human genetics)

Microbiology

Virology

Transfusion medicine

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

Within the given type of examination marked with **, the medical laboratory is permitted, without being required to inform and obtain prior approval from DAkKS, the modification, development and refinement of examination procedures.

The test procedures are given by way of an example. The laboratory has an up-to-date list of all test procedures within the flexible accreditation range.

The requirements for the management system in DIN EN ISO 15189 are written in a language relevant to medical laboratories and are generally in accordance with the principles of DIN EN ISO 9001.

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

The certificate together with its annex reflects the status at the time of the date of issue. The current status of the scope of accreditation can be found in the database of accredited bodies of Deutsche Akkreditierungsstelle GmbH.

<https://www.dakks.de/en/content/accredited-bodies-dakks>

Medical laboratory field: Clinical Chemistry

Type of examination:

Aggregometry*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Blood sedimentation	EDTA blood	Kinetic flow analysis in capillaries on photometric basis
Platelet function	Citrate blood, buffered	Impedance aggregometry
Platelet function	Citrate blood	Aggregation, capillary occlusion time

Type of examination:

Chromatography (gas chromatography (GC))**

Analyte (measurement parameter)	Test material (matrix)	Test technique
Benzene	EDTA blood (HS)	GC/HS
Ethanol	Serum, EDTA plasma, urine	GC/HS
Methanol	Serum	GC/HS
Methanol	Urine	GC/HS
Toluene	EDTA blood (HS)	GC/HS
Xylene	EDTA blood (HS)	GC/HS

Type of examination:

Chromatography (gas chromatography – mass spectrometry (GC-MS))**

Analyte (measurement parameter)	Test material (matrix)	Test technique
Cannabis (THC) quantitative	Urine	GC/MS
Drug screening (amphetamines, ecstasy, cocaine, opiates, cannabis, methadone, buprenorphine) qualitative, quantitative	Meconium	GC/MS
Drug screening (amphetamines, ecstasy, cocaine, opiates, cannabis, barbiturates, methadone, buprenorphine) qualitative, quantitative	Serum	GC/MS
Drug screening (amphetamines (incl. ecstasy), cocaine, opiates, methadone, benzodiazepines, tricyclic antidepressants, neuroleptics, analgesics, PCP, buprenorphine)	Urine	GC/MS
Levetiracetam	Serum, EDTA plasma	GC/MS
Lamotrigine	Serum	GC/MS

Annex to the accreditation certificate D-ML-13413-01-00

Analyte (measurement parameter)	Test material (matrix)	Test technique
Methadone	Serum	GC/MS
Opiate differentiation	Urine	GC/MS
Qualitative drug confirmation (amphetamines (incl. ecstasy), cocaine, opiates, methadone, EDDP, benzodiazepines, tricyclic antidepressants, PCP, buprenorphine)	Urine	GC/MS

Type of examination:

Chromatography (high-performance liquid chromatography (HPLC))*

Analyte (measurement parameter)	Test material (matrix)	Test technique
5-hydroxy-indole-acetic-acid	Urine	HPLC with electrochemical detection
Adrenalin	Urine	HPLC with electrochemical detection
Amiodaron	Serum	HPLC with UV detection
Ampicillin	Serum, EDTA plasma	HPLC with UV detection
Cefepime	Serum, EDTA plasma	HPLC with UV detection
Ceftazidime	Serum, EDTA plasma	HPLC with UV detection
Desethylamiodarone	Serum	HPLC with UV detection
Dopamine	Urine	HPLC with electrochemical detection
HbA1c	EDTA blood	HPLC with UV/VIS detection
HbA2	EDTA blood	HPLC with UV/VIS detection
HbF	EDTA blood	HPLC with UV/VIS detection
Homovanillic acid	Urine	HPLC with electrochemical detection
Linezolid	Serum, EDTA plasma	HPLC with UV detection
Meropenem	Serum, EDTA plasma	HPLC with UV detection
Metanephrine	Urine	HPLC with electrochemical detection
Noradrenalin	Urine	HPLC with electrochemical detection
Normetanephrine	Urine	HPLC with electrochemical detection
Piperacillin	Serum, EDTA plasma	HPLC with UV detection
Vanillylmandelic acid	Urine	HPLC with electrochemical detection
Vitamin A (retinol)	Serum	HPLC with UV detection
Vitamin B1 (thiamine diphosphate)	EDTA blood	HPLC with fluorescence detection
Vitamin B2 (FAD)	EDTA blood	HPLC with fluorescence detection
Vitamin B2 as total riboflavina	EDTA blood	HPLC with fluorescence detection

Analyte (measurement parameter)	Test material (matrix)	Test technique
Vitamin B6 (pyridoxal phosphate)	EDTA blood, serum	HPLC with fluorescence detection
Vitamin C (ascorbic acid)	Serum	HPLC with UV detection
Vitamin E (tocopherol)	Serum	HPLC with UV detection

Type of examination:

Chromatography (immune chromatography (IC))*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Drug screening	Urine	Immunochromatographic one-step test
Leucocytes/Lactoferrin	Stool	Immunochromatographic rapid test
Pregnancy test	Urine	Immunochromatographic rapid test
Troponin T	EDTA blood	Immunochromatographic rapid test

Type of examination:

Chromatography (immune chromatography (IC))*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Alprazolam	Serum, EDTA plasma	LC-MS/MS
Amitriptyline	Serum, EDTA plasma	LC-MS/MS
Aripiprazole	Serum, EDTA plasma	LC-MS/MS
Benzodiazepine	Serum, EDTA plasma	LC-MS/MS
Bromazepam	Serum, EDTA plasma	LC-MS/MS
Citalopram	Serum, EDTA plasma	LC-MS/MS
Clobazam	Serum, EDTA plasma	LC-MS/MS
Clomipramine	Serum, EDTA plasma	LC-MS/MS
Clonazepam	Serum, EDTA plasma	LC-MS/MS
Clozapine	Serum, EDTA plasma	LC-MS/MS
Cyclosporin A	EDTA blood	LC-MS/MS
Dehydro-aripiprazole	Serum, EDTA plasma	LC-MS/MS
Desalkyl-flurazepam	Serum, EDTA plasma	LC-MS/MS
Desipramine	Serum, EDTA plasma	LC-MS/MS
Desmethyl-clobazam	Serum, EDTA plasma	LC-MS/MS
N-desmethyl-citalopram	Serum, EDTA plasma	LC-MS/MS
N-Desmethyl-clozapine	Serum, EDTA plasma	LC-MS/MS
N-desmethyl-escitalopram	Serum, EDTA plasma	LC-MS/MS
N-desmethyl-olanzapine	Serum, EDTA plasma	LC-MS/MS
Desmethyl-sertraline	Serum, EDTA plasma	LC-MS/MS
Diazepam	Serum, EDTA plasma	LC-MS/MS
Doxepin	Serum, EDTA plasma	LC-MS/MS
Escitalopram	Serum, EDTA plasma	LC-MS/MS

Annex to the accreditation certificate D-ML-13413-01-00

Analyte (measurement parameter)	Test material (matrix)	Test technique
Ethosuximide	Serum, EDTA plasma	LC-MS/MS
Everolimus	EDTA blood	LC-MS/MS
Flunitrazepam	Serum, EDTA plasma	LC-MS/MS
Fluoxetine	Serum, EDTA plasma	LC-MS/MS
Flurazepam	Serum, EDTA plasma	LC-MS/MS
Gabapentin	Serum, EDTA plasma	LC-MS/MS
Haloperidol	Serum, EDTA plasma	LC-MS/MS
Imipramine	Serum, EDTA plasma	LC-MS/MS
Lacosamide	Serum, EDTA plasma	LC-MS/MS
Lorazepam	Serum, EDTA plasma	LC-MS/MS
Maprotiline	Serum, EDTA plasma	LC-MS/MS
Methylmalonic acid	Serum, EDTA plasma	LC-MS/MS
Midazolam	Serum, EDTA plasma	LC-MS/MS
Mirtazapine	Serum, EDTA plasma	LC-MS/MS
Nitrazepam	Serum, EDTA plasma	LC-MS/MS
Norclomipramine	Serum, EDTA plasma	LC-MS/MS
Nordiazepam	Serum, EDTA plasma	LC-MS/MS
Nordoxepin	Serum, EDTA plasma	LC-MS/MS
Norfluoxetine	Serum, EDTA plasma	LC-MS/MS
Nortriptyline	Serum, EDTA plasma	LC-MS/MS
Norquetiapine	Serum, EDTA plasma	LC-MS/MS
Olanzapine	Serum, EDTA plasma	LC-MS/MS
Oxazepam	Serum, EDTA plasma	LC-MS/MS
Ocarbazepine	Serum, EDTA plasma	LC-MS/MS
Paroxetine	Serum, EDTA plasma	LC-MS/MS
Phosphatidyl-ethanol	EDTA blood, EDTA capillary blood	LC-MS/MS
Pregabalin	Serum, EDTA plasma	LC-MS/MS
Primidone	Serum, EDTA plasma	LC-MS/MS
Quetiapine	Serum, EDTA plasma	LC-MS/MS
Risperidone	Serum, EDTA plasma	LC-MS/MS
9-OH-risperidone (paliperidone)	Serum, EDTA plasma	LC-MS/MS
Sertraline	Serum, EDTA plasma	LC-MS/MS
Sirolimus	EDTA blood	LC-MS/MS
Sultiame	Serum, EDTA plasma	LC-MS/MS
Tacrolimus (FK506)	EDTA blood	LC-MS/MS
Temazepam	Serum, EDTA plasma	LC-MS/MS
Tetrazepam	Serum, EDTA plasma	LC-MS/MS
Topiramate	Serum, EDTA plasma	LC-MS/MS
Trimipramine	Serum, EDTA plasma	LC-MS/MS

Analyte (measurement parameter)	Test material (matrix)	Test technique
O-desmethyl-venlafaxine	Serum, EDTA plasma	LC-MS/MS
Venlafaxine	Serum, EDTA plasma	LC-MS/MS
Zonisamide	Serum, EDTA plasma	LC-MS/MS
10-OH-carbamazepine	Serum, EDTA plasma	LC-MS/MS
25-OH-vitamin D3	Serum, EDTA and Li-heparin plasma	LC-MS/MS

Type of examination:

Flow cytometry (incl. including blood cell counting)*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Complete blood count	EDTA blood	Flow cytometric cell number determination and differentiation (fluorescence intensity), resistance measurement with hydronamic focusing, photometry
Small blood count	EDTA blood	Flow cytometric cell number determination and differentiation (fluorescence intensity), resistance measurement with hydronamic focusing, photometry
Erythrocytes	EDTA blood	Resistance measurement with hydronamic focusing
Reticulocyte hemoglobin content (Ret-Hb)	EDTA blood	Flow cytometric cell number determination and differentiation (fluorescence intensity), photometry
MCH	EDTA blood	Calculation
MCHC	EDTA blood	Calculation
MCV	EDTA blood	Calculation
Hemoglobin	EDTA blood	Photometry
Hematocrit	EDTA blood	Cumulative pulse height summation
Leucocytes	Ascites, joint and pleural punctate	Resistance measurement with hydronamic focusing
Leucocytes	Dialysates (only in the context of patient diagnostics)	Resistance measurement with hydronamic focusing
Liquor cell count – autom.	Liquor	Resistance measurement with hydronamic focusing
Reticulocytes	EDTA blood	Flow cytometric cell number determination and differentiation (fluorescence intensity)
Reticulocyte reproduction index	EDTA blood	Calculation

Analyte (measurement parameter)	Test material (matrix)	Test technique
Thrombocytes	Citrate blood	Resistance measurement with hydronamic focusing, flow cytometric cell number determination and differentiation (fluorescence intensity)

**Type of examination:
Electrochemical examinations***

Analyte (measurement parameter)	Test material (matrix)	Test technique
Chloride	Serum, urine, heparin plasma	ISE, indirect
Potassium	Serum, urine, heparin plasma	ISE, indirect
Sodium	Serum, urine, heparin plasma, dialysate (only in the context of patient diagnostics)	ISE, indirect

**Type of examination:
Electrophoresis***

Analyte (measurement parameter)	Test material (matrix)	Test technique
CDT	Serum	Capillary zone electrophoresis
Protein electrophoresis	Serum	Capillary zone electrophoresis
HB electrophoresis	EDTA blood	Capillary zone electrophoresis
Differentiation of renal proteinuria pattern (tubular proteins, albumin and glomerular proteins)	24-hours collection urine, urine	gel electrophoresis

**Type of examination:
Coagulometry***

Analyte (measurement parameter)	Test material (matrix)	Test technique
Anti-factor Xa heparin	Citrate plasma	Photometry (chromogenic method)
Anti-factor Xa organan	Citrate plasma	Photometry (chromogenic method)
Anti-factor Xa activity (apixaban, functional test)	Citrate plasma	Photometry (chromogenic method)
Anti-factor Xa activity (edoxaban, functional test)	Citrate plasma	Photometry (chromogenic method)
Anti-factor Xa activity (xarelto, functional test)	Citrate plasma	Photometry (chromogenic method)
APC ratio	Citrate plasma	Photometry (coagulometric method)
AT3	Citrate plasma	Photometry (chromogenic method)

Annex to the accreditation certificate D-ML-13413-01-00

Analyte (measurement parameter)	Test material (matrix)	Test technique
C1 esterase inhibitor (functional)	Citrate plasma	Photometry (chromogenic method)
Factor II	Citrate plasma	Photometry (coagulometric method)
Factor IX	Citrate plasma	Photometry (coagulometric method)
Factor V	Citrate plasma	Photometry (coagulometric method)
Factor VII	Citrate plasma	Photometry (coagulometric method)
Factor VIII	Citrate plasma	Photometry (coagulometric method)
Factor X	Citrate plasma	Photometry (coagulometric method)
Factor XI	Citrate plasma	Photometry (coagulometric method)
Factor VII	Citrate plasma	Photometry (coagulometric method)
Factor XIII	Citrate plasma	Photometry (chromogenic method)
Fibrinogen	Citrate plasma	Photometry (chromogenic method)
INR	Citrate plasma	Calculation
Lupus anticoagulant	Citrate plasma	Photometry (coagulometric method)
Plasma exchange test	Citrate plasma	Photometry (coagulometric method)
Plasminogen	Citrate plasma	Photometry (chromogenic method)
Protein C	Citrate plasma	Photometry (chromogenic method)
PTT	Citrate plasma	Photometry (coagulometric method)
Quick	Citrate plasma	Photometry (coagulometric method)
Thrombin time	Citrate plasma	Photometry (coagulometric method)
Thrombin time (dabigatran, functional test)	Citrate plasma	Photometry (coagulometric method)

Type of examination:

Ligand assays*

Analyte (measurement parameter)	Test material (matrix)	Test technique
ACTH	EDTA plasma	LIEMA
17-OH-progesterone	Serum	RIA
25-OH-vitamin D	Serum	CLIA
AFP	Serum	CLIA
Aldosterone	Serum, urine	CLIA
Amphetamines	Urine	CEDIA
Androstenedione	Serum	RIA
Anti-Müller hormone	Serum, Li-heparin plasma	ELISA
Anti-TPO-auto antibody	Serum	CLIA
Barbiturates	Urine	CEDIA
Benzodiazepines	Urine	CEDIA
Beta-HCG/tumor marker	Serum	CMIA
BNP	EDTA plasma	CLIA
Buprenorphine	Urine	CEDIA
CA 125	Serum	CLIA
CA 15-3	Serum	CLIA
CA 19-9	Serum	CLIA
CA 50	Serum , EDTA and heparin plasma	RIA
Calcitonin	Serum, heparin plasma	LEIA
Calprotectin	Stool	ELISA
Cannabis	Urine	CEDIA
Carbamazepine	Serum	CMIA
CCP	Serum	ELIA
CEA	Serum	CLIA
Chromogranin A	Serum, heparin plasma	RIA
Cortisol	Serum	CLIA
Cortisol	Urine	RIA
Cotinine	Serum, urine	LEIA
C peptide	Serum, heparin plasma	LIEMA
Cyfra 21-1	Serum, dipotassium EDTA plasma	ECLIA
DHEA-S	Serum	CLIA
Digitoxin	Serum, heparin plasma	CLIA
Digoxin	Serum	CLIA
Erythropoietin (EPO)	Serum, heparin plasma	LEIA
Ethyl glucuronide	Urine	EIA
Ferritin	Serum, heparin plasma, liquor	CLIA
Folic acid	Serum	CLIA
Folic acid in erythrocytes	EDTA blood	CLIA
Free testosterone	Serum	RIA
FT3	Serum	CLIA

Annex to the accreditation certificate D-ML-13413-01-00

Analyte (measurement parameter)	Test material (matrix)	Test technique
FT4	Serum	CLIA
FSH	Serum	CLIA
Gastrin	Serum	LIEMA
Gentamicin	Serum, EDTA, Li-heparin plasma	CLIA
HCG	Serum	CLIA
Histamine	EDTA plasma	IRMA
Holo-transcobalamin (active vitamin B12)	Serum	CMIA
Homocysteine	Serum	CLIA
IGF-1 (somatomedin C)	Serum, heparin plasma	LIEMA
IGF-3	Serum, heparin plasma	LEIA
Inhibin B	Serum	ELISA
Insulin	Serum, heparin plasma	LIEMA
HOMA index	Serum, heparin plasma	Calculation
Interleukin 2 receptor	EDTA plasma	LIEMA
Cocaine	Urine	CEDIA
LH	Serum	CLIA
Methadone (EDDP)	Urine	CEDIA
Methadone	Urine	CEDIA
Methotrexate	EDTA plasma	CMIA
Myoglobin	Serum, heparin plasma	CLIA
NSE	Serum, liquor	CLIA
NT-proBNP	Serum	CLIA
Estradiol	Serum	CMIA
Opiates	Urine	EIA
Ostasis	Serum	CLIA
Osteocalcin	Serum	CLIA
Pancreas-elastase 1	Stool	ELISA
Paracetamol	Serum	Homogeneous enzyme immunoassay
Parathormone	EDTA plasma	CLIA
Phencyclidine	Urine	CEDIA
Phenobarbital	Serum, EDTA, heparin plasma	CMIA
Phenytoin	Serum	CMIA
Procalcitonin	Serum, heparin plasma	CLIA
Progesterone	Serum	CLIA
Procollagen-3-peptide	Serum	RIA
Prolactin	Serum	CLIA
PSA, complexed	Serum	CLIA
PSA, free	Serum	CLIA
PSA, total	Serum	CLIA
Renin (active)	EDTA plasma	CLIA

Annex to the accreditation certificate D-ML-13413-01-00

Analyte (measurement parameter)	Test material (matrix)	Test technique
S-100 protein	Serum, liquor	CLIA
SCC	Serum	CMIA
SHBG	Serum	CLIA
STH (hGH)	Serum, heparin plasma	LIEMA
T3 total	Serum	CLIA
T4 total	Serum	CLIA
Testosterone (total)	Serum	CLIA
Theophylline	Serum	CMIA
Thymidine kinase	Serum	CLIA
Thyroglobulin	Serum, heparin plasma	LIEMA
Tobramycin	Serum	Homogeneous enzyme immunoassay
TPA	Serum	CLIA
Troponin I, highly sensitive	Serum, Li-heparin plasma	CLIA
Tryptase	Serum, EDTA and heparin plasma	FEIA
TSH	Serum	CLIA
Valproic acid	Serum	CMIA
Vancomycin	Serum	CMIA
Vitamin B12	Serum	CLIA
Vitamin D1,25-(OH) ₂ -D3	Serum	CLIA

Type of examination:

Lysis reactions**

Analyte (measurement parameter)	Test material (matrix)	Test technique
Osmotic resistance	Heparin blood	Visual method

Type of examination:

Microscopy*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Differential blood count, microscopic	Blood smear, EDTA blood	Pappenheim coloration
Dysmorphic erythrocytes	Urine	Microscopy
Fragmentocytes	EDTA blood	Coloration, microscopy
Reticulocytes, manual	EDTA blood	Coloration, microscopy
Synovial analysis	Synovial punctate	Direct count in cell chamber
Thrombocytes count acc. to Fonio	EDTA blood	Microscopy
Urine sediment	Urine	Microscopy
Cell count (total)	Liquor	Microscopy
Cell count (total)	Dialysate (only in the context of patient diagnostics), pleura, ascites, punctate	Microscopy

Type of examination:

Osmometry*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Osmolality	Serum, urine, 24-hours collection urine	Freezing point depression (cryoscopy)

Type of examination:

Qualitative examinations (simple) with visual evaluation*

Analyte (measurement parameter)	Test material (matrix)	Test technique
pH value	Stool	Test strip
Occult blood	Stool	Colour test
Urine status	Urine	Test strip

Type of examination:

Spectrometry (immunoturbidimetry/turbidimetry)*

Analyte (measurement parameter)	Test material (matrix)	Test technique
ASL	Serum, heparin plasma	Immunoturbidimetry
CRP	Serum, EDTA plasma, heparin plasma	Immunoturbidimetry
D dimers	Citrate plasma	Turbidimetry
Total protein	Liquor, urine, dialysate	Turbidimetry
Hemoglobin (iFOBT)	Stool	Latex agglutination immunoturbidimetry
Haptoglobin	Serum	Immunoturbidimetry
Lipoprotein A	Serum	Immunoturbidimetry
Protein S, free	Citrate plasma	Turbidimetry
Protein S activity	Citrate plasma	Turbidimetry
Transferrin	Serum, heparin and EDTA plasma	Immunoturbidimetry
von-Willebrandt factor	Citrate plasma	Turbidimetry
von-Willebrandt factor antigen	Citrate plasma	Turbidimetry

Type of examination:

Spectrometry (UV/VIS photometry)*

Analyte (measurement parameter)	Test material (matrix)	Test technique
ACE	Serum	Kinetic
Alkaline phosphatase	Serum, heparin plasma	Photometry
Ammonia	EDTA plasma	Enzymatic colour test
Inorganic phosphor	Serum, heparin plasma	Photometric UV test
Antioxidative capacity	Serum, EDTA plasma	Photometry
Bilirubin	Serum of newborns	Spectral photometry
Bilirubin, direct	Serum, heparin plasma	Photometric colour test / DPD

Annex to the accreditation certificate D-ML-13413-01-00

Analyte (measurement parameter)	Test material (matrix)	Test technique
Bilirubin, total	Serum, EDTA, heparin plasma	Photometric colour test
Bilirubin, indirect	Serum, heparin plasma	Calculation
Calcium	Serum, heparin plasma, urine	Photometric colour test
Calcium-creatinine quotient	Urine	Calculation
Calcium, corrected	Serum, heparin plasma	Calculation
Cholestenone	Serum, EDTA, heparin plasma	CHOD-PAP method
Cholinesterase	Serum, heparin plasma	Kinetic colour test
CK-MB (isoenzyme of creatine kinase)	Serum, heparin plasma	Kinetic UV test
Creatine kinase	Serum, heparin plasma	Kinetic UV test
Iron	Serum, heparin plasma	TPTZ, colour test
Iron-binding capacity	Serum, heparin plasma	Calculation
Ethanol	Serum	Enzymatic colour test
Fructosamine	Serum, EDTA, heparin plasma	Photometry
Bile acid	Serum, EDTA plasma	Photometry
Total protein	Serum, EDTA, heparin plasma	Biuret method, colour test
Total peroxidase	Serum, EDTA plasma	Photometry
GLDH	Serum, EDTA, heparin plasma	UV test, standardized method (DGKC)
Glucose	Serum, NaF blood, liquor, urine, citrate-fluoride blood (GlucoEXACT)	Hexokinase method, enzymatic UV test
Glucose quotient CSF/serum	Serum, liquor	Calculation
Glucose tolerance test	Serum, heparin plasma, NaF blood, citrate-fluoride blood (GlucoEXACT)	Hexokinase method, enzymatic UV test
GOT	Serum, EDTA, heparin plasma	Kinetic UV test acc. to IFCC (with pyridoxal phosphate)
GPT	Serum, EDTA, heparin plasma	Kinetic UV test acc. to IFCC (with pyridoxal phosphate)
Uric acid	Serum, EDTA, heparin plasma, urine	Enzymatic colour test /uricase POD
Urea	Serum, Li-heparin plasma, urine, dialysate, (only in the context of patient diagnostics)	Kinetic UV test
Urea N	Serum, heparin plasma, dialysate, (only in the context of patient diagnostics)	Calculation
HBDH	Serum, heparin plasma	Optimized standard method according to DGKC
HDL cholesterol	Serum, heparin plasma	Enzymatic colour test
Creatinine	Serum, heparin plasma, urine	Jaffé method, kinetic colour test
Creatinine / creatinine clearance	Serum, EDTA, heparin plasma, urine	Calculation
Creatinine clearance	Serum, EDTA, heparin plasma, urine	Calculation

Analyte (measurement parameter)	Test material (matrix)	Test technique
GFR	Serum	Calculation
Lithium	Serum	Photometry
Lactate	NaF blood, liquor	Enzymatic colour test
LDH	Serum, heparin plasma	Kinetic UV test acc. to IFCC
LDL cholesterol	Serum, heparin plasma	Enzymatic colour test
LDL cholesterol -Friede.	Serum	Calculation
Lipase	Serum, EDTA, heparin plasma	Kinetic colour test
Magnesium	Serum, heparin plasma, urine	Photometric colour test
Pancreas amylase	Serum, heparin plasma	Enzymatic colour test
Phosphate	Urine	Photometric colour test
Phosphate clearance	Serum, urine	Calculation
Acid phosphatase	Serum, heparin plasma	Kinetic UV test
Transferrin saturation	Serum, heparin, EDTA plasma	Calculation
Triglycerides	Serum, heparin plasma	GPO-PAP method, enzymatic colour test
α amylase	Serum, urine	Kinetic colour test acc. to IFCC
γ GT	Serum, EDTA, heparin plasma	Kinetic colour test acc. to IFCC

Type of examination:

Spectrometry (atom absorption spectrometry (AAS))**

Analyte (measurement parameter)	Test material (matrix)	Test technique
Lead	EDTA blood, metal-heparin blood	AAS tube
Copper	Serum, metal-heparin, whole blood	AAS tube
Selenium	Serum, metal-heparin, whole blood	AAS tube
Zinc	Serum, metal-heparin, whole blood	AAS flame

Type of examination:

Spectrometry (nephelometry)*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Albumin	Serum, liquor	Nephelometry
Albumin	Serum, heparin and EDTA plasma, 24-hours collection urine, urine	Nephelometry
CRP, sensitive	Serum, heparin and EDTA plasma	Nephelometry
Cystatin C	Serum, heparin plasma	Latex test nephelometry
Soluble transferrin receptor	Serum, heparin plasma	Latex test nephelometry
α 1 antitrypsin	Serum, heparin and EDTA plasma	Nephelometry
α 1 micro globulin	Urine	Nephelometry
β 2 micro globulin	Serum, plasma, 24-hours collection urine, urine	Nephelometry
β trace protein	Ear and nasal secretion, liquor, serum, heparin and EDTA plasma	Nephelometry

Medical laboratory field: Immunology

Type of examination:

Electrophoresis**

Analyte (measurement parameter)	Test material (matrix)	Test technique
Immunofixation	Serum, 24-hours collection urine, urine	Gel electrophoresis
Oligoclonal IgG antibody	Serum, liquor	Isoelectric focusing

Type of examination:

Ligand assays*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Acetylcholine receptor antibody	Serum, EDTA plasma	RRA
ANA screen IgG antibody	Serum, EDTA, heparin, citrate plasma	ELISA
Anti-cardiolipin IgA antibody	Serum, heparin and EDTA plasma	ELIA
Anti-cardiolipin IgG antibody	Serum, heparin and EDTA plasma	ELIA
Anti-cardiolipin IgM antibody	Serum, heparin and EDTA plasma	ELIA
Anti-dsDNA IgG antibody	Serum, heparin, EDTA, citrate plasma	EIA
Anti-ENA profile plus 2 IgG antibody	Serum, EDTA, heparin, citrate plasma	ELISA
Anti-GBM IgG antibody	Serum, heparin and EDTA plasma	ELIA
Anti-tissue transglutaminase IgA antibody	Serum, EDTA, citrate plasma	ELIA
Anti-tissue transglutaminase IgG antibody	Serum, EDTA, citrate plasma	ELIA
Anti-gliadin IgA antibody	Serum, heparin and EDTA plasma	ELIA
Anti-gliadin IgG antibody	Serum, heparin and EDTA plasma	ELIA
Intrinsic factor antibody	Serum, heparin, EDTA and citrate plasma	ELISA
Anti-MPO IgG antibody	Serum, EDTA, heparin, citrate plasma	FEIA
Anti-PR3-hn-hr-IgG antibody	Serum, EDTA, heparin, citrate plasma	FEIA
C1q-binding circulating immune complexes	Serum, EDTA plasma	ELISA
CXCL13	Liquor	ELISA
ECP	Serum	FEIA
Single-stranded DNA antibody	Serum	ELISA
Gangliosides D1b-IgG antibody	Serum	ELISA
Gangliosides D1b-IgM antibody	Serum	ELISA
Gangliosides M1-IgG antibody	Serum	ELISA

Analyte (measurement parameter)	Test material (matrix)	Test technique
Gangliosides M1-IgM antibody	Serum	ELISA
Gangliosides Q1B-IgG antibody	Serum	ELISA
Gangliosides Q1b-IgM antibody	Serum	ELISA
Histone IgG antibody	Serum, EDTA, citrate plasma	ELISA
HIT II antibody	Serum, plasma with trisodium citrate or EDTA plasma	ELISA
Human tau antigen	Liquor	ELISA
Insulin antibody	Serum	IRMA
IgE	Serum, EDTA and heparin plasma	FEIA
IL6	Serum	CMIA
Myelin-associated glycoprotein IgM antibody	Serum	ELISA
Parietal cell antibody	Serum	ELISA
Phosphatidylserine IgG antibody	Serum, heparin, EDTA and citrate plasma	EIA
Phosphatidylserine IgM antibody	Serum, heparin, EDTA and citrate plasma	EIA
Phosphor tau protein	Liquor	ELISA
Quantiferon TB gold	Heparin blood	Cell stimulation, ELISA
RAST (specific IgE, IgG and IgG4)	Serum, plasma	FEIA
Rheumatoid factor IgA	Serum, heparin and EDTA plasma	FEIA
Rheumatoid factor IgG	Serum, heparin and EDTA plasma	FEIA
Rheumatoid factor IgM	Serum, heparin and EDTA plasma	FEIA
Thyroglobulin auto antibody	Serum	CLIA
TSH receptor antibody	Serum	ELISA
β 2-glycoprotein-IgG antibody	Serum, heparin and EDTA plasma	ELIA
β 2-glycoprotein-IgM antibody	Serum, heparin and EDTA plasma	ELIA
β -amyloid (1-42)	Liquor	ELISA
β -amyloid (1-40)	Liquor	ELISA
β -amyloid 42/40 quot.	Liquor	ELISA

Type of examination:

Microscopy*

Analyte (measurement parameter)	Test material (matrix)	Test technique
ANA (antinuclear antibodies)	Serum, EDTA, heparin, citrate plasma	IFT
Antibodies against endomysium (GLF)	Serum, EDTA, heparin, citrate plasma	IFT
Antibodies against smooth muscles (SMA)	Serum, EDTA, heparin, citrate plasma	IFT
Antibodies against Hep-2 cells	Serum, EDTA, heparin, citrate plasma, punctate	IFT

Annex to the accreditation certificate D-ML-13413-01-00

Analyte (measurement parameter)	Test material (matrix)	Test technique
Antibodies against LKM	Serum, EDTA, heparin, citrate plasma	IFT
Antimitochondrial antibodies (AMA)	Serum, EDTA, heparin, citrate plasma	IFT
C-ANCA	Serum, EDTA, heparin, citrate plasma	IFT
Neuronal auto antibody (Hu,RiYo)	Serum, plasma	IFT
p-ANCA	Serum, EDTA, heparin, citrate plasma	IFT

Type of examination:

Spectrometry (immunoturbidimetry/turbidimetry)*

Analyte (measurement parameter)	Test material (matrix)	Test technique
IgA	Serum, heparin plasma	Immunoturbidimetry
IgG	Serum, heparin plasma	Immunoturbidimetry
IgG sub classes	Serum, heparin and EDTA plasma	Turbidimetry
IgM	Serum, heparin plasma	Immunoturbidimetry
Complement C3	Serum	Turbidimetry
Complement C4	Serum	Turbidimetry
Free kappa light chains, quant.	Serum	Turbidimetry
Free lambda light chains, quant.	Serum	Turbidimetry
Rheumatic factor	Serum, heparin plasma	Immunoturbidimetry

Type of examination:

Spectrometry (nephelometry)*

Analyte (measurement parameter)	Test material (matrix)	Test technique
IgA	Liquor	Latex test nephelometry
IgA	Serum	Nephelometry
IgG	Serum, liquor, urine, 24-hours	Nephelometry
IgM	Liquor	Latex test nephelometry
IgM	Serum	Nephelometry
Light chains, kappa type	Serum, 24-hours collection urine	Nephelometry
Light chains, lambda type	Serum, 24-hours collection urine	Nephelometry

Medical laboratory field: Human genetics (molecular human genetics)

Type of examination:

Molecular biological examinations (amplification method)*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Factor II (prothrombin) genetic mutation (G20210A), wild type, hetero and homozygote)	EDTA, citrate blood	Real time PCR, pain curve analysis
Factor V genetic mutation (Leiden genetic mutation) (G1691A), wild type, hetero and homozygote for G169A)	EDTA, citrate blood	Real time PCR, pain curve analysis
Hemochromatosis HFE genetic mutation (C187G (H63D); A193T (S65/C); G845A (C282Y) wild type hetero and homozygote	EDTA, citrate blood	Real time PCR, pain curve analysis
MTHFR gene (methylene-tetrahydrofolate-reductase) point mutation C 677 T (Ala223Val) and A 1298 C (Glu430Ala)	EDTA, citrate blood	Real time PCR, pain curve analysis

Medical laboratory field: Microbiology

Type of examination:

Agglutination tests*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Aspergillus antibody	Serum	Indirect hemagglutination
Candida dubliniensis	Culture material from the following patient materials: Vascular catheters, liquor, wound swabs, intraoperative swabs (patient material), abscess swabs, intraabdominal swabs, punctates (pleural, CNS, intraabdominal, joint, abscess punctate), blood culture, tissue samples, near bone swabs, cervical swabs, urogenital swabs, ejaculate, skin swabs, ear swabs (interna, externa), respiratory tract material, eye swabs, urine, stool	Latex agglutination
Cardiolipin micro flocculation test	Serum, EDTA plasma	Micro flocculation test
Echinococcus granulosus antibody	Serum	Indirect hemagglutination

Annex to the accreditation certificate D-ML-13413-01-00

Analyte (measurement parameter)	Test material (matrix)	Test technique
Enteropathogenic E. coli	Culture material from stool	Gruber agglutination
Mycoplasma pneumoniae antibody	Serum	Particle agglutination
Salmonella spp.	Culture material from the following patient materials: Vascular catheters, liquor, wound swabs, intraoperative swabs (patient material), abscess swabs, intraabdominal swabs, punctates (pleural, CNS, intraabdominal, joint, abscess punctate), blood culture, tissue samples, near bone swabs, cervical swabs, urogenital swabs, ejaculate, skin swabs, ear swabs (interna, externa), respiratory tract material, eye swabs, urine, stool	Gruber agglutination
Schistosomes antibody	Serum	IHA
Shigella spp.	Culture material from the following patient materials: Vascular catheters, liquor, wound swabs, intraoperative swabs (patient material), abscess swabs, intraabdominal swabs, punctates (pleural, CNS, intraabdominal, joint, abscess punctate), blood culture, tissue samples, near bone swabs, cervical swabs, urogenital swabs, ejaculate, skin swabs, ear swabs (interna, externa), respiratory tract material, eye swabs, urine, stool	Gruber agglutination
Streptococcus pneumoniae	Culture material from the following patient materials: Vascular catheters, liquor, wound swabs, intraoperative swabs (patient material), abscess swabs, intraabdominal swabs, punctates (pleural, CNS, intraabdominal, joint, abscess punctate), blood culture, tissue samples, near bone swabs, cervical swabs, urogenital swabs, ejaculate, skin swabs, ear swabs (interna, externa), respiratory tract material, eye swabs, urine, stool	Latex agglutination

Analyte (measurement parameter)	Test material (matrix)	Test technique
TPPA	Serum, heparin, EDTA and citrate plasma, liquor	Particle agglutination
Yersinia spp.	Culture material from the following patient materials: Vascular catheters, liquor, wound swabs, intraoperative swabs (patient material), abscess swabs, intraabdominal swabs, punctates (pleural, CNS, intraabdominal, joint, abscess punctate), blood culture, tissue samples, near bone swabs, cervical swabs, urogenital swabs, ejaculate, skin swabs, ear swabs (interna, externa), respiratory tract material, eye swabs, urine, stool	Gruber agglutination

Type of examination:

Chromatography (immunochromatography (IC))*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Hem. strep A antigen	Throat, tonsil swab	Immunochromatographic rapid test
Plasmodia (malaria) antigen	EDTA blood	Immunochromatographic rapid test
PBP2a protein	Culture material from the following patient materials: Vascular catheters, liquor, wound swabs, intraoperative swabs (patient material), abscess swabs, intraabdominal swabs, punctates (pleural, CNS, intraabdominal, joint, abscess punctate), blood culture, tissue samples, near bone swabs, cervical swabs, urogenital swabs, ejaculate, skin swabs, ear swabs (interna, externa), respiratory tract material, eye swabs, urine, stool	Immunochromatographic rapid test

**Type of examination:
bacteria and fungi susceptibility testing***

Analyte (measurement parameter)	Test material (matrix)	Test technique
Anaerobes	Culture material from the following patient materials: Abscess, wound and intraoperative swabs (patient material), liquor, punctates (pleural, CNS, intraabdominal, joint, abscess punctate), blood culture, tissue samples, cervical swabs, intraabdominal swabs, inner ear swabs, bronchoalveolar lavage	Microdilution
Demanding gram negatives (campylobacter, haemophilus spp., HACEK, Moraxella spp., Neisseria, Pasteurella spp.)	Culture material from the following patient materials: Eye, urogenital swab, liquor, vascular catheter, punctates (pleura, CNS, intraabdominal, joint abscess punctuate), ejaculate, blood culture, respiratory tract samples, abscess, wound, intraoperative swabs (patient material), tissue samples, intraabdominal swabs	Agar diffusion, gradient agar diffusion, chromogenic rapid test (Nitrocefim)
Enterobacterales	Culture material from the following patient materials: Vascular catheter, liquor, wound swabs, intraoperative swabs (patient material), abscess swabs, intraabdominal swabs, punctates (pleura, CNS, intraabdominal, joint, abscess punctate), blood culture, tissue samples, near bone swabs, cervical swabs, urogenital swabs, ejaculate, skin swabs, ear swabs (interna, externa), respiratory tract material, eye swabs, urine, stool	Microdilution (MHK), automated, modified Bouillon microdilution test, agar diffusion, gradient agar diffusion
Enterococci	Culture material from the following patient materials: Abscess, wound and intraoperative swabs (patient material), liquor, punctates (pleura, CNS, intraabdominal, joint, abscess punctate), blood culture, tissue samples, urogenital swabs, intraabdominal swabs, urine, vascular catheter	Automated Bouillon microdilution test, agar diffusion, gradient agar diffusion

Annex to the accreditation certificate D-ML-13413-01-00

Analyte (measurement parameter)	Test material (matrix)	Test technique
Yeasts	Culture material from the following patient materials: Vascular catheter, liquor, wound swabs, intraoperative swabs (patient material), abscess swabs, intraabdominal swabs, punctates (pleura, CNS, intraabdominal, joint, abscess punctate), blood culture, tissue samples, near bone swabs, cervical swabs, urogenital swabs, ejaculate, skin swabs, ear swabs (interna, externa), respiratory tract material, eye swabs, urine, stool	Microdilution
Nonfermenter (Acinetobacter spp., Pseudomonas spp., Stenotrophomonas)	Culture material from the following patient materials: Vascular catheter, liquor, wound swabs, intraoperative swabs (patient material), abscess swabs, intraabdominal swabs, punctates (pleura, CNS, intraabdominal, joint, abscess punctate), blood culture, tissue samples, near bone swabs, cervical swabs, urogenital swabs, ejaculate, skin swabs, ear swabs (interna, externa), respiratory tract material, eye swabs, urine, stool	Automated, modified Bouillon microdilution test, agar diffusion, gradient agar diffusion, microdilution (MHK),
Other gram positives (coryne bacteria, aerococci, listeria)	Culture material from the following patient materials: Urogenital swabs, liquor, vascular catheter, punctates (pleura, CNS, intraabdominal, joint, abscess punctate), ejaculate, blood culture, Abscess, wound, intraoperative swabs (patient material), tissue samples, near bone samples, intraabdominal swabs, urine	Agar diffusion, gradient agar diffusion

Analyte (measurement parameter)	Test material (matrix)	Test technique
Staphylococci	Culture material from the following patient materials: Vascular catheter, liquor, wound swabs, intraoperative swabs (patient material), abscess swabs, intraabdominal swabs, punctates (pleura, CNS, intraabdominal, joint, abscess punctate), blood culture, tissue samples, near bone swabs, cervical swabs, urogenital swabs, ejaculate, skin swabs, ear swabs (interna, externa), respiratory tract material, eye swabs, urine, stool	Automated, modified Bouillon microdilution test, agar diffusion, gradient agar diffusion
Streptococci (β -hemolytic, greening streptococci, pneumococci)	Culture material from the following patient materials: Vascular catheter, liquor, wound swabs, intraoperative swabs (patient material), abscess swabs, intraabdominal swabs, punctates (pleura, CNS, intraabdominal, joint, abscess punctate), blood culture, tissue samples, near bone swabs, cervical swabs, urogenital swabs, ejaculate, skin swabs, ear swabs (interna, externa), respiratory tract material, eye swabs, urine, stool from newborns	Automated, modified Bouillon microdilution test, agar diffusion, gradient agar diffusion, chromogenic

Type of examination:

Microbial differentiation/identification/typing*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Anaerobes	Culture material from the following patient materials: Abscess, wound and intraoperative swabs (patient material), liquor, punctates (pleural, CNS, intraabdominal, joint, abscess punctate), blood culture, tissue samples, cervical swabs, intraabdominal swabs, inner ear swabs, bronchoalveolar lavage	Mass spectrometry

Annex to the accreditation certificate D-ML-13413-01-00

Analyte (measurement parameter)	Test material (matrix)	Test technique
Demanding gram negatives (campylobacter, Hemophilus spp., HACEK, Moraxella spp., Pasteurella spp.)	Culture material from the following patient materials: Eye, urogenital swab, liquor, vascular catheter, punctates (pleura, CNS, intraabdominal, joint abscess punctate), ejaculate, blood culture, respiratory tract samples, abscess, wound, intraoperative swabs (patient material), tissue samples, intraabdominal swabs	Mass spectrometry
Dermatophytes	Culture material from the following patient materials: skin, hair, nails	Specific culture methods, in aerobic atmosphere on solid media, bright field microscopy unstained (after addition of potassium hydroxide solution)
Enterobacterales	Culture material from the following patient materials: Vascular catheter, liquor, wound swabs, intraoperative swabs (patient material), abscess swabs, intraabdominal swabs, punctates (pleura, CNS, intraabdominal, joint, abscess punctate), blood culture, tissue samples, near bone swabs, cervical swabs, urogenital swabs, ejaculate, skin swabs, ear swabs (interna, externa), respiratory tract material, eye swabs, urine, stool	Biochemically-orienting (oxidase), mass spectrometry, biochemically simple (Kligler)
Enterococci	Culture material from the following patient materials: Abscess, wound and intraoperative swabs (patient material), liquor, punctates (pleura, CNS, intraabdominal, joint, abscess punctate), blood culture, tissue samples, urogenital swabs, intraabdominal swabs, urine, vascular catheter	Mass spectrometry, automated biochemical identification
Gardnerella vaginalis	Culture material from the following patient materials: Urogenital swab, ejaculate	Mass spectrometry

Annex to the accreditation certificate D-ML-13413-01-00

Analyte (measurement parameter)	Test material (matrix)	Test technique
Yeasts	Culture material from the following patient materials: Vascular catheter, liquor, wound swabs, intraoperative swabs (patient material), abscess swabs, intraabdominal swabs, punctates (pleura, CNS, intraabdominal, joint, abscess punctate), blood culture, tissue samples, near bone swabs, cervical swabs, urogenital swabs, ejaculate, skin swabs, ear swabs (interna, externa), respiratory tract material, eye swabs, urine, stool	Mass spectrometry
Legionella	Culture material from the following patient materials: Samples from the lower respiratory tract	Mass spectrometry
Mycoplasma / ureaplasma	From liquid media for the following patient materials: Urogenital swab, ejaculate, urine, newborn swabs	Biochemically
Neisseria	Culture material from the following patient materials: ENT swab, eye swab, liquor, blood culture, urogenital swab, ejaculate, vascular catheter, punctates (pleura, CNS, intraabdominal, joint, abscess punctate), abscess, wound, intraoperative swabs (patient material), tissue samples, intraabdominal swabs	Mass spectrometry
Nocardia, actinomycetes	Culture material from the following patient materials: Pus, bronchial, tracheal secretions, sputum, punctates (pleura, CNS, intraabdominal, joint, abscess punctate), blood culture, abscess, wound, intraoperative swabs (patient material), tissue samples, intraabdominal swabs	Mass spectrometry

Annex to the accreditation certificate D-ML-13413-01-00

Analyte (measurement parameter)	Test material (matrix)	Test technique
Nonfermenter (Acinetobacter spp., Pseudomonas spp., Stenotrophomonas, Bordetella spp.)	Culture material from the following patient materials: Vascular catheter, liquor, wound swabs, intraoperative swabs (patient material), abscess swabs, intraabdominal swabs, punctates (pleura, CNS, intraabdominal, joint, abscess punctate), blood culture, tissue samples, near bone swabs, cervical swabs, urogenital swabs, ejaculate, skin swabs, ear swabs (interna, externa), respiratory tract material, eye swabs, urine, stool	Mass spectrometry, biochemically-orienting (oxidase)
Other gram positives (aerococci, bacillus spp., coryne bacteria, listeria)	Culture material from the following patient materials: Urogenital swabs, liquor, vascular catheter, punctates (pleura, CNS, intraabdominal, joint, abscess punctate), ejaculate, blood culture, abscess, wound, intraoperative swabs (patient material), tissue samples, near bone samples, intraabdominal swabs, urine	Mass spectrometry
Staphylococci	Culture material from the following patient materials: Vascular catheter, liquor, wound swabs, intraoperative swabs (patient material), abscess swabs, intraabdominal swabs, punctates (pleura, CNS, intraabdominal, joint, abscess punctate), blood culture, tissue samples, near bone swabs, cervical swabs, urogenital swabs, ejaculate, skin swabs, ear swabs (interna, externa), respiratory tract material, eye swabs, urine, stool	Mass spectrometry, biochemically simple-orienting (catalase, coagulase), automated biochemical identification

Annex to the accreditation certificate D-ML-13413-01-00

Analyte (measurement parameter)	Test material (matrix)	Test technique
Streptococci (β -hemolytic, greening streptococci, pneumococci)	Culture material from the following patient materials: Vascular catheter, liquor, wound swabs, intraoperative swabs (patient material), abscess swabs, intraabdominal swabs, punctates (pleura, CNS, intraabdominal, joint, abscess punctate), blood culture, tissue samples, near bone swabs, cervical swabs, urogenital swabs, ejaculate, skin swabs, ear swabs (interna, externa), respiratory tract material, eye swabs, urine, stool from newborns	Mass spectrometry, biochemically orienting (catalase), optochin, automated biochemical identification

**Type of examination:
Culture examinations***

Analyte (measurement parameter)	Test material (matrix)	Test technique
Anaerobes	Abscess, wound and intraoperative swabs (patient material), liquor, punctates (pleural, CNS, intraabdominal, joint, abscess punctate), blood culture, tissue samples, cervical swabs, intraabdominal swabs, inner ear swabs, bronchoalveolar lavage	Unspecific and specific culture methods in anaerobic atmosphere, in liquid and on solid media, blood culture methods, fully mechanized
Demanding gram negatives (Hemophilus spp., HACEK, Moraxella spp., Pasteurella spp.)	Eye, urogenital swab, liquor, vascular catheter, punctates (pleura, CNS, intraabdominal, joint abscess punctate), ejaculate, blood culture, respiratory tract samples, abscess, wound, intraoperative swabs (patient material), tissue samples, intraabdominal swabs	Unspecific and specific culture methods in CO ₂ -enriched atmosphere, in liquid and on solid media, blood culture methods, fully mechanized, inhibitor test
Bacillus spp.	Abscess, wound, intraoperative swabs (patient material), liquor, vascular catheter, punctates (pleura, CNS, intraabdominal, joint abscess punctate), blood culture, tissue samples, intraabdominal swabs	Unspecific and specific culture methods in aerobic and CO ₂ -enriched atmosphere, in liquid and on solid media, blood culture methods, fully mechanized, inhibitor test

Annex to the accreditation certificate D-ML-13413-01-00

Analyte (measurement parameter)	Test material (matrix)	Test technique
Dermatophytes	Skin, hair, nails	Specific culture methods in aerobic atmosphere on solid media
Enterobacterales	Vascular catheter, liquor, wound swabs, intraoperative swabs (patient material), abscess swabs, intraabdominal swabs, punctates (pleura, CNS, intraabdominal, joint, abscess punctate), blood culture, tissue samples, near bone swabs, cervical swabs, urogenital swabs, ejaculate, skin swabs, ear swabs (interna, externa), respiratory tract material, eye swabs, urine, stool	Unspecific and specific culture methods in aerobic atmosphere, in liquid and on solid media, blood culture methods, fully mechanized, inhibitor test
Enterococci	Abscess, wound and intraoperative swabs (patient material), liquor, punctates (pleura, CNS, intraabdominal, joint, abscess punctate), blood culture, tissue samples, urogenital swabs, intraabdominal swabs, urine, vascular catheter	Unspecific and specific culture methods in aerobic atmosphere, in liquid and on solid media, blood culture methods, fully mechanized, inhibitor test
Gardnerella vaginalis	Urogenital swab, ejaculate	Specific culture methods in CO ₂ -enriched atmosphere on solid media
Yeasts	Vascular catheter, liquor, wound swabs, intraoperative swabs (patient material), abscess swabs, intraabdominal swabs, punctates (pleura, CNS, intraabdominal, joint, abscess punctate), blood culture, tissue samples, near bone swabs, cervical swabs, urogenital swabs, ejaculate, skin swabs, ear swabs (interna, externa), respiratory tract material, eye swabs, urine, stool	Unspecific and specific culture methods in aerobic atmosphere, in liquid and on solid media, blood culture methods, fully mechanized, inhibitor test
Legionella	Samples from the lower respiratory tract	Specific culture methods in CO ₂ -enriched atmosphere on solid media
Mycoplasma / ureaplasma	Urogenital swab, ejaculate, urine, newborn swabs	Specific culture methods in anaerobic atmosphere in liquid media

Annex to the accreditation certificate D-ML-13413-01-00

Analyte (measurement parameter)	Test material (matrix)	Test technique
Neisseria	ENT swab, eye swab, liquor, blood culture, urogenital swab, ejaculate, vascular catheter, punctates (pleura, CNS, intraabdominal, joint, abscess punctate), abscess, wound, intraoperative swabs (patient material), tissue samples, intraabdominal swabs	Unspecific and specific culture methods in CO ₂ -enriched atmosphere, in liquid and on solid media, blood culture methods, fully mechanized, inhibitor test
Nocardia, actinomycetes	Pus, bronchial, tracheal secretions, sputum, punctates (pleura, CNS, intraabdominal, joint, abscess punctate), blood culture, abscess, wound, intraoperative swabs (patient material), tissue samples, intraabdominal swabs	Unspecific and specific culture methods in anaerobic atmosphere, in liquid and on solid media, blood culture methods, fully mechanized
Nonfermenter (<i>Pseudomonas</i> spp., <i>Acinetobacter</i> spp., <i>Stenotrophomonas</i> , <i>Bordetella</i> spp.)	Vascular catheter, liquor, wound swabs, intraoperative swabs (patient material), abscess swabs, intraabdominal swabs, punctates (pleura, CNS, intraabdominal, joint, abscess punctate), blood culture, tissue samples, near bone swabs, cervical swabs, urogenital swabs, ejaculate, skin swabs, ear swabs (interna, externa), respiratory tract material, eye swabs, urine, stool	Unspecific and specific culture methods in anaerobic atmosphere, in liquid and on solid media, blood culture methods, fully mechanized, inhibitor test
Other gram positives (coryne bacteria, aerococci, listeria)	Urogenital swabs, liquor, vascular catheter, punctates (pleura, CNS, intraabdominal, joint, abscess punctate), ejaculate, blood culture, abscess, wound, intraoperative swabs (patient material), tissue samples, near bone samples, intraabdominal swabs, urine	Unspecific and specific culture methods in aerobic and CO ₂ -enriched atmosphere, in liquid and on solid media, blood culture methods, fully mechanized, inhibitor test

Annex to the accreditation certificate D-ML-13413-01-00

Analyte (measurement parameter)	Test material (matrix)	Test technique
Staphylococci	Vascular catheter, liquor, wound swabs, intraoperative swabs (patient material), abscess swabs, intraabdominal swabs, punctates (pleura, CNS, intraabdominal, joint, abscess punctate), blood culture, tissue samples, near bone swabs, cervical swabs, urogenital swabs, ejaculate, skin swabs, ear swabs (interna, externa), respiratory tract material, eye swabs, urine, stool	Unspecific and specific culture methods in aerobic atmosphere, in liquid and on solid media, blood culture methods, fully mechanized, inhibitor test
Streptococci (β -hemolytic, greening streptococci, pneumococci)	Vascular catheter, liquor, wound swabs, intraoperative swabs (patient material), abscess swabs, intraabdominal swabs, punctates (pleura, CNS, intraabdominal, joint, abscess punctate), blood culture, tissue samples, near bone swabs, cervical swabs, urogenital swabs, ejaculate, skin swabs, ear swabs (interna, externa), respiratory tract material, eye swabs, urine, stool from newborns	Unspecific and specific culture methods in aerobic and CO ₂ -enriched atmosphere, in liquid and on solid media, blood culture methods, fully mechanized, inhibitor test

Type of examination:

Ligand assays*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Bordetella pertussis toxin IgA antibody	Serum, heparin, EDTA and citrate plasma	ELISA
Bordetella pertussis toxin IgG antibody	Serum, heparin, EDTA and citrate plasma	ELISA
Bordetella FHA-IgA antibody	Serum, heparin, EDTA and citrate plasma	ELISA
Bordetella FHA-IgG antibody	Serum, heparin, EDTA and citrate plasma	ELISA
Borrelia burgdorferi IgG antibody	Serum, heparin, EDTA and citrate plasma	ELISA
Borrelia burgdorferi IgG antibody	Liquor	ELISA
Borrelia burgdorferi IgM antibody	Serum, heparin, EDTA and citrate plasma	ELISA
Borrelia burgdorferi IgM antibody	Liquor	ELISA
Pathogen-specific IgG antibody against Borrelia burgdorferi in CNS	Serum, liquor	ELISA

Annex to the accreditation certificate D-ML-13413-01-00

Analyte (measurement parameter)	Test material (matrix)	Test technique
Borrelia burgdorferi IgG antibody	Serum, liquor	Chip immunoblot
Pathogen-specific IgM antibody against Borrelia burgdorferi in CNS	Liquor, serum	ELISA
Borrelia burgdorferi IgM antibody	Serum, liquor	Chip immunoblot
Campylobacter spp.	Stool	CLIA
Candida albicans IgA antibody	Serum, citrate plasma	ELISA
Candida albicans IgG antibody	Serum, citrate plasma	ELISA
Candida albicans IgM antibody	Serum, citrate plasma	ELISA
Chlamydomphila pneumoniae IgA antibody	Serum	ELISA
Chlamydomphila pneumoniae IgG antibody	Serum	ELISA
Chlamydomphila trachomatis IgA antibody	Serum	ELISA
Chlamydia trachomatis IgA antibody	Seminal plasma	ELISA
Chlamydia trachomatis IgG antibody	Serum	ELISA
Clostridium difficile GDH	Stool	CLIA
Clostridium difficile Toxin A/B	Stool	CLIA
Cryptosporidia	Stool	EIA
Diphtheria toxoid IgG antibody	Serum, heparin, EDTA and citrate plasma	ELISA
EHEC	Stool	EIA
Entamoeba histolytica	Stool	EIA
Giardia lamblia	Stool	EIA
Helicobacter pylori	Stool	EIA
Helicobacter pylori IgA antibody	Serum, heparin, EDTA and citrate plasma	EIA
Helicobacter pylori IgG antibody	Serum, heparin, EDTA and citrate plasma	EIA
Helicobacter pylori IgA antibody	Serum	Chip immunoblot
Helicobacter pylori IgG antibody	Serum	Chip immunoblot
Legionella pneum. antigen	Urine	FIA
Lues IgG / IgM blot	Serum, liquor	Immunoblot
Mycoplasma pneumoniae IgA antibody	Serum, heparin, EDTA and citrate plasma	ELISA
Mycoplasma pneumoniae IgG antibody	Serum, heparin, EDTA and citrate plasma	ELISA
Mycoplasma pneumoniae IgM-A	Serum, heparin, EDTA and citrate plasma	ELISA
Pneumococci antigen	Urine	FIA

Annex to the accreditation certificate D-ML-13413-01-00

Analyte (measurement parameter)	Test material (matrix)	Test technique
Pathogen-specific antibodies against <i>Treponema pallidum</i> in the CNS	Serum, heparin, EDTA and citrate plasma, liquor	Indirect particle immunoassay
Tetanus toxoid IgG antibody	Serum, heparin, EDTA and citrate plasma	ELISA
<i>Toxoplasma gondii</i> IgG antibody	Serum, heparin, EDTA and citrate plasma	CLIA
<i>Toxoplasma gondii</i> IgM antibody	Serum, heparin, EDTA and citrate plasma	CLIA
<i>Treponema pallidum</i> antibody (screening test IgG and IgM)	Serum, heparin, EDTA and citrate plasma	CLIA
<i>Yersinia</i> species IgA blot	Serum	Chip immunoblot
<i>Yersinia</i> species IgG blot	Serum	Chip immunoblot
<i>Yersinia</i> species IgA antibody	Serum, heparin and EDTA plasma	ELISA
<i>Yersinia</i> species IgG antibody	Serum, heparin and EDTA plasma	ELISA

Type of examination:

Microscopy*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Bacteria and fungi	Original material, culture material	Bright field microscopy (Gram stain)
<i>Cryptococcus neoformans</i>	Liquor, culture material	Bright field microscopy
Dermatophytes and sprout fungi	Skin, hair, nails	Brightfield microscopy unstained (after addition of potassium hydroxide solution)
Dermatophytes and moulds	Culture material	Brightfield microscopy (with lactophenol cotton blue)
<i>Echinococcus granulosus</i> IgG antibody	Serum, heparin, EDTA and citrate plasma	IFT
Plasmodia (malaria)	Blood smear, EDTA blood	Microscopy after staining
Parasites	Stool, urine	Bright field microscopy
<i>Pneumocystis jirovecii</i> antigen	Lavage, BAL, sputum	IFT direct
<i>Toxoplasma gondii</i> antibody in CNS	Serum, heparin, EDTA and citrate plasma, liquor	IFT
<i>Toxoplasma gondii</i> IgG antibody	Serum, heparin, EDTA and citrate plasma	IFT
<i>Toxoplasmosis gondii</i> antibody (polyvalent)	Serum, heparin, EDTA and citrate plasma	IFT

Type of examination:

Molecular-biological examinations (amplification method)**

Analyte (measurement parameter)	Test material (matrix)	Test technique
Bordetella pertussis DNA	Nose and throat swab, BAL, sputum	Real-time PCR
Bordetella parapertussis DNA	Nose and throat swab, BAL, sputum	Real-time PCR
Carbapenemases of enterobacterales	Culture material	Qualitative real-time PCR
Chlamydia trachomatis DNA	Urine, sperm, cervical or urethral swab	TMA
Meningitis pathogen bacterial	Liquor	Qualitative multiplex PCR
MRSA direct detection	Bacterial DNA from direct swab	Real-time PCR
Neisseria gonorrhoeae	Urine, sperm, cervical or urethral swab	TMA
Mycobacterium tuberculosis (MTB) complex DNA	Sputum, sputum sediment	Qualitative real-time PCR
Pathogenic E. coli	Culture material, stool samples	Real-time PCR
PVL (Panton-Valentine leucocidin) gen	Culture material, human swabs	Real-time PCR

Medical laboratory field: Virology

Type of examination:

Chromatography (immunochromatography (IC))*

Analyte (measurement parameter)	Test material (matrix)	Test technique
RSV rapid test	Nose swab	Immunochromatographic rapid test

Type of examination:

Ligand assays*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Adenovirus	Stool	EIA
Anti-HIV 1/2 confirmation response	Serum, heparin, EDTA and citrate plasma	Immunoblot
Anti-HAV antibody, total	Serum	CLIA
Anti-HAV IgM antibody	Serum	CLIA
Anti-HBc antibody, total	Serum	CLIA
Anti-HBc antibody	Serum	CLIA
Anti-HBc-IgM antibody	Serum	CLIA
Anti-HBe antibody	Serum	CLIA

Annex to the accreditation certificate D-ML-13413-01-00

Analyte (measurement parameter)	Test material (matrix)	Test technique
Anti-HBs antibody	Serum	CLIA
Anti-HCV antibody	Serum	CLIA
Anti-HDV antibody	Serum	CLIA
Anti-HIV antibody/HIV p24 antigen	Serum	CLIA
Astrovirus	Stool	EIA
Coronavirus SARS-CoV-2-IgG	Serum, EDTA plasma	CLIA
Coronavirus SARS-CoV-2-IgM	Serum, EDTA plasma	CLIA
Coxsackie virus IgA antibody	Serum, heparin, EDTA and citrate plasma	ELISA
Coxsackie viruses IgG	Serum, heparin, EDTA and citrate plasma	ELISA
Coxsackie viruses IgM	Serum, heparin, EDTA and citrate plasma	ELISA
CMV IgG	Serum, heparin, EDTA and citrate plasma	CLIA
CMV IgM	Serum, heparin, EDTA and citrate plasma	CLIA
EBV-VCA IgG antibody	Serum, heparin, EDTA and citrate plasma	CLIA
EBV-VCA IgM antibody	Serum, heparin, EDTA and citrate plasma	CLIA
EBV-EBNA-1 IgG antibody	Serum, heparin, EDTA and citrate plasma	CLIA
Enteroviruses (echo, cox., entero virus 68-71) IgA	Serum, heparin and EDTA plasma	ELISA
Enteroviruses (echo, cox., entero virus 68-71) IgG	Serum, heparin and EDTA plasma	ELISA
Enteroviruses (echo, cox., entero virus 68-71) IgM	Serum, heparin and EDTA plasma	ELISA
Pathogen-specific antibodies against cytomegalovirus in the CNS	Serum, liquor	ELISA
Pathogen-specific antibodies against Epstein-Barr virus in the CNS	Serum, liquor	ELISA
Pathogen-specific antibodies against FSME virus in the CNS	Serum, liquor	ELISA
Pathogen-specific antibodies against herpes simplex virus in the CNS	Serum, liquor	ELISA
Pathogen-specific antibodies against measles virus in the CNS	Serum, liquor	ELISA
Pathogen-specific antibodies against mumps virus in the CNS	Serum, liquor	ELISA

Annex to the accreditation certificate D-ML-13413-01-00

Analyte (measurement parameter)	Test material (matrix)	Test technique
Pathogen-specific antibodies against rubella virus in the CNS	Serum, liquor	ELISA
Pathogen-specific antibodies against Varizella zoster virus in the CNS	Serum, liquor	ELISA
FSME virus IgG	Serum, heparin and EDTA plasma	ELISA
FSME virus IgM	Serum, heparin and EDTA plasma	ELISA
HBe antigen	Serum	CLIA
HBs antigen	Serum	CLIA
Hepatitis C virus antibody	Serum, heparin, EDTA and citrate plasma	Immunoblot
Hepatitis E virus IgG antibody	Serum, heparin, EDTA and citrate plasma	ELISA
Hepatitis E virus IgM antibody	Serum, heparin, EDTA and citrate plasma	ELISA
Herpes virus type 4-IgG antibody (avidity)	Serum, heparin, EDTA and citrate plasma	Immunoblot
HIV-P24 antigen	Serum, heparin, EDTA and citrate plasma	EIA
HSV1/2-IgG antibody	Serum, heparin, EDTA and citrate plasma	EIA
HSV1/2-IgM antibody	Serum, heparin, EDTA and citrate plasma	EIA
Measles IgG antibody	Serum, heparin, EDTA and citrate plasma	EIA
Measles IgM antibody	Serum, heparin and EDTA plasma	EIA
Mumps IgM antibody	Serum, heparin and EDTA plasma	EIA
Mumps IgG antibody	Serum, heparin, EDTA and citrate plasma	EIA
Norovirus	Stool	EIA
Parvovirus B19-IgG antibody (avidity)	Serum, heparin, EDTA and citrate plasma	Immunoblot
Parvovirus IgG antibody	Serum, citrate plasma	CLIA
Parvovirus IgM antibody	Serum, citrate plasma	CLIA
Rotavirus	Stool	EIA
Rubella IgG antibody	Serum, heparin, EDTA and citrate plasma	EIA
Rubella IgM antibody	Serum, heparin, EDTA and citrate plasma	CLIA
Varizella zoster IgG antibody	Serum, heparin, EDTA and citrate plasma	EIA
Varizella zoster IgA antibody	Serum, citrate plasma	EIA
Varizella zoster IgM antibody	Serum, heparin, EDTA and citrate plasma	EIA

Type of examination:

Molecular biological examinations (amplification methods)**

Analyte (measurement parameter)	Test material (matrix)	Test technique
CMV, quantitative	EDTA blood, liquor, urine, BAL, biopsy, stool, swab	Real-time PCR
SARS-CoV-2 (COVID-19)	Nose and throat swab, swab of saliva samples, throat lavage solution, sputum, BAL	Real-time PCR
SARS-CoV-2 (COVID-19)	Nose and throat swab, swab of saliva samples, throat lavage	TMA
EBV DNA	EDTA blood, liquor, BAL, sputum	Real-time PCR
HPV high-risk screening	Swab (endocervical)	TMA
HPV 16 18/45 genotype	Swab (endocervical)	TMA
HSV type I and II	Dry swab, liquor	Real-time PCR
Influenza A (+H1N1)	Dry swab	Real-time PCR
Influenza A (+H1N1)	Dry swab	Multiplex real-time PCR
Influenza B	Dry swab	Real-time PCR
Influenza B	Dry swab	Multiplex real-time PCR
Influenza A+B	Nose and throat swab	Real-time PCR
Measles virus RNA	Throat swab, urine, EDTA plasma, liquor	Real-time PCR
Meningitis pathogen viral	Liquor	Qualitative multiplex PCR
Norovirus	Stool	Real-time PCR
Respiratory pathogen panel	Nasopharyngeal aspirates, nasopharyngeal swabs, sputum, BAL	Multiplex real-time PCR
Varizella zoster virus (VZV)	Liquor, dry swab, vesicle content, EDTA blood	Real-time PCR

Medical laboratory field: Transfusion medicine

Type of examination:

Agglutination tests*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Antigen determination A2, Cw, Fy(a), Fy(b), H, Jk(a), Jk(b), k Cellano, Kp(a), Kp(b), Le(a), Le (b), Lu(a), M, N, P1, S, s, Wr(a)	EDTA blood	Column agglutination, agglutination
Antibody identification	EDTA blood	Column agglutination
Antibody screening test	EDTA blood	Column agglutination
Antibody titre determination	EDTA blood	Column agglutination
Blood typing, large: ABO + Rh (D) + antibodies + Rh formula + Kell	EDTA blood	Column agglutination
Blood typing, small: ABO + Rh (D) + antibodies	EDTA blood	Column agglutination
Blood typing: newborns + fetal	EDTA blood	Column agglutination
Direct Coombs test screening	EDTA blood	Column agglutination
Serological compatibility test	EDTA blood	Column agglutination, agglutination