



مختبر فرايبورج الطبي
FREIBURG MEDICAL LABORATORY MIDDLE EAST (L.L.C.)

A member of
SYNLAB

Flexible Scope of Accreditation

Period of validity: 22.05.2023 to 21.05.2028

Date of issue: 26.04.2025

Freiburg Medical Laboratory, Middle East (L.L.C)

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Tests in the field:

Medical Laboratory Diagnosis

Medical Analytical Fields:

Clinical Chemistry

Immunology

Humangenetics (Molecular Genetics)

Transfusion Medicine

Microbiology

Virology

The medical laboratory is permitted within the specified areas marked with* the free choice of standard or equivalent test methods, without being required to inform and obtain prior approval from DAkkS.

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

This certificate annex is only valid together with the written accreditation certificate and reflects the status as indicated by the date of issue. The current status of any given scope of accreditation can be found in the directory of accredited bodies maintained by Deutsche Akkreditierungsstelle GmbH at <https://www.dakks.de>.

Medicinal Analytical field: Clinical Chemistry

Type of test:

Chromatography (High Pressure Liquid Chromatography (HPLC))*

Analyte (measurement parameter)	Test material (matrix)	Test technique	Procedure/Version	Instrument	CE Kit	Date of New/Changed/Deleted Parameters
HbF	EDTA Blood	HPLC	SOP/HP/05/C	Variant II	x	
HbA1	EDTA Blood	HPLC	SOP/HP/05/C	Variant II	x	

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HbA2	EDTA Blood	HPLC	SOP/HP/05/C	Variant II	x	
HbD	EDTA Blood	HPLC	SOP/HP/05/C	Variant II	x	
HbS	EDTA Blood	HPLC	SOP/HP/05/C	Variant II	x	
HbC	EDTA Blood	HPLC	SOP/HP/05/C	Variant II	x	
HbA1c DCCT	EDTA Blood	HPLC	SOP/BC/09/I	BioRad D-10	x	
HbA1c IFCC	EDTA Blood	HPLC	SOP/BC/09/I	BioRad D-10	x	

Type of test:
Electrochemical tests*

Analyte (measurement parameter)	Test material (matrix)	Test technique	Procedure/Version	Instrument	CE Kit	Date of New/Changed/Deleted Parameters
Chloride	Serum, Heparin Plasma, Urine	ISE	SOP/BC/04/K & SOP/BC/05/L	Cobas c503	x	
Potassium	Serum, Heparin Plasma, Urine	ISE	SOP/BC/04/K & SOP/BC/05/L	Cobas c503	x	
Sodium	Serum, Heparin Plasma, Urine	ISE	SOP/BC/04/K & SOP/BC/05/L	Cobas c503	x	

Type of test:
Flow cytometry (including blood cell counting)*

Analyte (measurement parameter)	Test material (matrix)	Test technique	Procedure/Version	Instrument	CE Kit	Date of New/Changed/Deleted Parameters
Differential Blood Count	EDTA Blood	Flow cytometry	SOP/HE/05/F	Sysmex	x	
Hematocrit	EDTA Blood	RBC pulse height detection	SOP/HE/05/F	Sysmex	x	
Hemoglobin	EDTA Blood	SLS-Hemoglobin	SOP/HE/05/F	Sysmex	x	
Platelets	EDTA Blood	Hydro Dynamic Focusing	SOP/HE/05/F	Sysmex	x	
RBC Index MCH	EDTA Blood	Calculation	SOP/HE/05/F	Sysmex	x	
RBC Index MCHC	EDTA Blood	Calculation	SOP/HE/05/F	Sysmex	x	
RBC Index MCV	EDTA Blood	Calculation	SOP/HE/05/F	Sysmex	x	
Red Blood Cells	EDTA Blood	Hydro Dynamic Focusing	SOP/HE/05/F	Sysmex	x	
White Blood Cell Count	EDTA Blood	Flow cytometry	SOP/HE/05/F	Sysmex	x	

Type of Test:
Ligand assays*

Analyte (measurement parameter)	Test material (matrix)	Test technique	Procedure / Version	Instrument	CE Kit	Date of New/Changed/Deleted Parameters
ACTH	EDTA Plasma	ECLIA	SOP/IM/02/O	Cobas e801	x	
AFP	Serum, Heparin Plasma, EDTA Plasma	ECLIA	SOP/IM/01/J	Cobas e411	x	
Aldosterone	Serum, EDTA Plasma	CLIA	SOP/IM/23/A	Liasion Diasorin	x	
Aldost./Renin Ratio	Serum, EDTA Plasma	CALC	SOP/IM/23/A	Liasion Diasorin	x	
AMH	Serum, Heparin Plasma	ECLIA	SOP/IM/02/O	Cobas e801	x	
Androstenedione	Serum	ECLIA	SOP/IM/26/A	Cobas e801	x	
Beta-crosslaps	Serum	ECLIA	SOP/IM/27/A	Cobas Pure	x	
Bioavailable Testosterone	Serum, Heparin Plasma, EDTA Plasma	Calculation	SOP/IM/02/O	Cobas e801	x	

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CA 125	Serum, Heparin Plasma, EDTA Plasma	ECLIA	SOP/IM/01/J	Cobas e411	x	
CA 15-3	Serum, Heparin Plasma, EDTA Plasma	ECLIA	SOP/IM/01/J	Cobas e411	x	
CA 19-9	Serum, Heparin Plasma, EDTA Plasma	ECLIA	SOP/IM/01/J	Cobas e411	x	
C-Peptide	Serum, Heparin Plasma, EDTA Plasma	ECLIA	SOP/IM/25/A	Cobas e801	x	
Calcitonin	Serum	ECLIA	SOP/IM/29/A	Cobas Pure	x	26.07.2024
Calprotectin	Stool	CLIA	SOP/SE/11/B	Liasion Diasorin	x	
Pancreatic Elastase	Stool	CLIA	SOP/SE/11/B	Liasion Diasorin	x	
Carbamazepine	Serum, Heparin Plasma, EDTA Plasma	MAIA	SOP/BC/06/L	Cobas c503	x	
CEA	Serum, Heparin Plasma, EDTA Plasma	ECLIA	SOP/IM/01/J	Cobas e411	x	
CK-MB	Serum, Heparin Plasma, EDTA Plasma	ECLIA	SOP/IM/05/J	Cobas e801	x	
Cortisol	Serum, Heparin Plasma, EDTA Plasma	ECLIA	SOP/IM/02/O	Cobas e411	x	
DHEA-S	Serum, Heparin Plasma, EDTA Plasma	ECLIA	SOP/IM/02/O	Cobas e801	x	
Drug screening	Urine	IA	SOP/BC/08/K	Manual	x	
Estradiol	Serum, Heparin Plasma, EDTA Plasma	ECLIA	SOP/IM/02/O	Cobas e801	x	
Folate	Serum, Heparin Plasma	ECLIA	SOP/IM/03/M	Cobas e801	x	
Free PSA	Serum, Heparin Plasma, EDTA Plasma	ECLIA	SOP/IM/01/J	Cobas e411	x	
Free PSA %	Serum	Calculation	SOP/IM/01/J	Cobas e411	x	
Free T3	Serum, Heparin Plasma, EDTA Plasma	ECLIA	SOP/IM/10/M	Cobas e801	x	
Free T4	Serum, Heparin Plasma, EDTA Plasma	ECLIA	SOP/IM/10/M	Cobas e801	x	
Free Testosterone	Serum, Heparin Plasma, EDTA Plasma	Calculation	SOP/IM/02/O	Cobas e801	x	
FSH	Serum, Heparin Plasma, EDTA Plasma	ECLIA	SOP/IM/02/O	Cobas e801	x	
Haemoglobin	Stool	IA (Faecal Occult Blood)	SOP/IM/28/A	Manual		
HCG+Beta	Serum, Heparin Plasma, EDTA Plasma	ECLIA	SOP/IM/02/O	Cobas e801	x	
HCG+Beta, free	Serum	ECLIA	SOP/IM/17/I	Cobas e801	x	
Homa Index	Serum, Heparin Plasma, EDTA Plasma	Calculation	SOP/IM/19/G	Cobas e801	x	
IGF_1	Serum, Heparin Plasma, EDTA Plasma	ECLIA	SOP/IM/24/B	Cobas e801	x	
Insulin	Serum, Heparin Plasma, EDTA Plasma	ECLIA	SOP/IM/19/G	Cobas e801	x	

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LH	Serum, Heparin Plasma, EDTA Plasma	ECLIA	SOP/IM/02/O	Cobas e801	x	
NT-Pro BNP	Serum, Li-Heparin Plasma, Na-Heparin Plasma, EDTA plasma	ECLIA	SOP/IM/22/B	Cobas e801		
PAPP-A	Serum	ECLIA	SOP/IM/18/I	Cobas e801	x	
Progesterone	Serum, Heparin Plasma, EDTA Plasma	ECLIA	SOP/IM/02/O	Cobas e801	x	
Prolactin	Serum, Heparin Plasma, EDTA Plasma	ECLIA	SOP/IM/02/O	Cobas e801	x	
PTH, intact	EDTA Plasma, Serum	ECLIA	SOP/IM/06/K	Cobas e801	x	
Renin	EDTA Plasma	CLIA	SOP/IM/23/A	Liasion Diasorin	x	
SHBG	Serum, Li-Heparin Plasma	ECLIA	SOP/IM/02/O	Cobas e801	x	
Testosterone	Serum, Heparin Plasma, EDTA Plasma	ECLIA	SOP/IM/02/O	Cobas e801	x	
Thyroglobulin (TG)	Serum, Heparin Plasma, EDTA Plasma	ECLIA	SOP/IM/01/J	Cobas e411	x	
Total PSA	Serum, Heparin Plasma, EDTA Plasma	ECLIA	SOP/IM/01/J	Cobas e411	x	
Total T3	Serum, Heparin Plasma, EDTA Plasma	ECLIA	SOP/IM/10/M	Cobas e801	x	
Total T4	Serum, Heparin Plasma, EDTA Plasma	ECLIA	SOP/IM/10/M	Cobas e801	x	
Troponin T, high sensitive	Serum, Heparin Plasma, EDTA Plasma	ECLIA	SOP/IM/05/J	Cobas e801	x	
TSH	Serum, Heparin Plasma, EDTA Plasma	ECLIA	SOP/IM/10/M	Cobas e801	x	
Valproic Acid	Serum, Heparin Plasma, EDTA Plasma	EIA	SOP/BC/10/J	Cobas c503	x	
Vitamin B12	Serum, Heparin Plasma, EDTA Plasma	ECLIA	SOP/IM/03/M	Cobas e801	x	
Vitamin D (25OH)	Serum, Heparin Plasma, EDTA Plasma	ECLIA	SOP/IM/03/M	Cobas e801	x	

Type of Test:
Microscopy

Analyte (measurement parameter)	Test material (matrix)	Test technique	Procedure/Version	Instrument	CE Kit	Date of New/Changed/Deleted Parameters
Differential Blood Count (manual)	EDTA Blood, Smear	Microscopy	SOP/HE/06/E	Manual	x	
Urine sediment	Urine	Microscopy	SOP/U/01/B	Manual	x	

Type of Test:
Coagulation*

Analyte (measurement parameter)	Test material (matrix)	Test technique	Procedure/Version	Instrument	CE Kit	Date of New/Changed/Deleted Parameters
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aPTT	Citrated Plasma	Optical Clot Detection	SOP/C/06/A	ACL Elite Pro	x	
Fibrinogen	Citrated Plasma	Optical Clot Detection	SOP/C/07/A	ACL Elite Pro	x	
INR	Citrated Plasma	Calculation	SOP/C/05/B	ACL Elite Pro	x	
Lupus Anticoagulants	Citrated Plasma	Optical Clot Detection	SOP/C/08/A	ACL Elite Pro	x	
PT	Citrated Plasma	Optical Clot Detection	SOP/C/05/B	ACL Elite Pro	x	

Type of Test:
Spectrometry (UV-VIS-Photometry)*

Analyte (measurement parameter)	Test material (matrix)	Test technique	Procedure/Version	Instrument	CE Kit	Date of New/Changed/ Deleted Parameters
Albumin	Serum, Heparin Plasma, EDTA Plasma	Photometry VIS	SOP/BC/02/L	Cobas c503	x	
Alkaline Phosphatase	Serum, Heparin Plasma	Photometry VIS	SOP/BC/01/M	Cobas c503	x	
ALT	Serum, Heparin Plasma, EDTA Plasma	Photometry UV	SOP/BC/01/M	Cobas c503	x	
Ammonia	EDTA Plasma	Photometry UV	SOP/BC/02/L	Cobas c503	x	
Amylase	Serum, Heparin Plasma, Urine	Photometry VIS	SOP/BC/01/M	Cobas c503	x	
AST	Serum, Heparin Plasma, EDTA Plasma	Photometry UV	SOP/BC/01/M	Cobas c503	x	
Bicarbonate	Serum	Photometry VIS	SOP/BC/15/F	Cobas c503	x	
Bile acids, total	Serum	Photometry VIS	SOP/BC/17 E	Cobas c503 (CDC)	x	
Bilirubin direct	Serum, Heparin Plasma	Photometry VIS	SOP/BC/02/L	Cobas c503	x	
Bilirubin total	Serum, Heparin Plasma, EDTA Plasma	Photometry VIS	SOP/BC/02/L	Cobas c503	x	
BUN/Creatinine ratio	Serum, Heparin Plasma, EDTA Plasma	Calculation	SOP/BC/02/L	Cobas c503	x	
BUN/Urea	Serum, Heparin Plasma, EDTA Plasma, Urine	Photometry UV	SOP/BC/02/L	Cobas c503	x	
Calcium	Serum, Heparin Plasma, Urine	Photometry UV	SOP/BC/02/L	Cobas c503	x	
Cholesterol	Serum, Heparin Plasma, EDTA Plasma	Photometry VIS	SOP/BC/02/L	Cobas c503	x	
CK	Serum, Heparin Plasma, EDTA Plasma	Photometry UV	SOP/BC/01/M	Cobas c503	x	
Copper	Serum, Heparin Plasma, EDTA Plasma	Photometry VIS	SOP/BC/17 E	Cobas c503 (CDC)	x	
Creatinine	Serum, Heparin Plasma, EDTA Plasma, Urine	Photometry VIS	SOP/BC/02/L	Cobas c503	x	
Ethanol	Serum, EDTA Plasma, Urine	Photometry UV	SOP/BC/07/K	Cobas c503	x	
G6PDH	EDTA Blood	Photometry UV	SOP/BC/18/B	Cobas c503 (CDC)	x	
GGT	Serum, Heparin Plasma, EDTA Plasma	Photometry VIS	SOP/BC/01/M	Cobas c503	x	
Glucose	NaF Plasma, Serum, Heparin Plasma, EDTA Plasma, CSF, Urine	Photometry UV	SOP/BC/14/F	Cobas c503	x	
HDL-Cholesterol	Serum, Heparin Plasma, EDTA Plasma	Photometry VIS	SOP/BC/02/L	Cobas c503	x	

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Homocysteine	EDTA plasma, Heparin Plasma, Serum	Photometry UV	SOP/BC/12/G	Cobas c503	x	
Iron	Serum, Heparin Plasma	Photometry VIS	SOP/BC/02/L	Cobas c503	x	
Lactate	NaF Plasma, CSF	Photometry VIS	SOP/BC/02/L	Cobas c503	x	
LDH	Serum, Heparin Plasma, EDTA Plasma	Photometry UV	SOP/BC/01/M	Cobas c503	x	
LDL Friedewald	Serum, Heparin Plasma	Calculation	SOP/BC/02/L	Cobas c503	x	
LDL-Cholesterol	Serum, Heparin Plasma	Photometry VIS	SOP/BC/02/L	Cobas c503	x	
Lipase	Serum, Heparin Plasma	Photometry VIS	SOP/BC/01/M	Cobas c503	x	
Magnesium	Serum, Heparin Plasma, Urine	Photometry VIS	SOP/BC/02/L	Cobas c503	x	
Pancreatic Amylase	Serum, Heparin Plasma	Photometry VIS	SOP/BC/01/M	Cobas c503	x	
Phosphorus	Serum, Heparin Plasma, EDTA Plasma, Urine	Photometry UV	SOP/BC/02/L	Cobas c503	x	
Protein	Serum, Heparin Plasma, EDTA Plasma, Urine, CSF	Photometry VIS	SOP/BC/02/L	Cobas c503	x	
Triglycerides	Serum, Heparin Plasma, EDTA Plasma	Photometry VIS	SOP/BC/02/L	Cobas c503	x	
UIBC	Serum, Heparin Plasma	Photometry VIS	SOP/BC/02/L	Cobas c503	x	
Uric acid	Serum, Heparin Plasma, EDTA Plasma, Urine	Photometry VIS	SOP/BC/02/L	Cobas c503	x	
Zinc	Serum	Photometry VIS	SOP/BC/17/E	Cobas c503 (CDC)	x	

Type of Test:

Spectrometry (Turbidimetry)*

Analyte (measurement parameter)	Test material (matrix)	Test technique	Procedure/Version	Instrument	CE Kit	Date of New/Changed/Deleted Parameters
Albumin	Urine, CSF	Turbidimetry	SOP/BC/03/M	Cobas c503	x	
Albumin/Creatinine Ratio	Urine	Calculation	SOP/BC/03/M	Cobas c503	x	
Antistreptolysin O	Serum, Heparin Plasma, EDTA Plasma	Turbidimetry	SOP/BC/03/M	Cobas c503	x	
Apolipoprotein A1	Serum, Heparin Plasma, EDTA Plasma	Turbidimetry	SOP/BC/03/M	Cobas c503	x	
Apolipoprotein B1	Serum, Heparin Plasma, EDTA Plasma	Turbidimetry	SOP/BC/03/M	Cobas c503	x	24.07.2024
Ceruloplasmin	Serum	Turbidimetry	SOP/BC/03/M	Cobas c503	x	
CRP	Serum, Heparin Plasma, EDTA Plasma	Turbidimetry	SOP/BC/03/M	Cobas c503	x	
CRP HS	Serum, Heparin Plasma	Turbidimetry	SOP/BC/19/B	Cobas c503	x	
Cystatin C	Serum, Heparin Plasma, EDTA Plasma	Turbidimetry	SOP/BC/11/G	Cobas c503	x	
D-Dimer	Citrated Plasma	Turbidimetry	SOP/BC/16/D	Cobas c503	x	
Estimated Average Glucose	EDTA Blood	Calculation	SOP/BC/09/I	BioRad D-10	x	
Ferritin	Serum, Heparin Plasma, EDTA Plasma	Turbidimetry	SOP/BC/03/M	Cobas c503	x	

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Glomerular Filtration Rate/GFR	Serum, Heparin Plasma, EDTA Plasma	Calculation	SOP/BC/11/G	Cobas c503	x	
Haptoglobin	Serum, Heparin Plasma, EDTA Plasma	Turbidimetry	SOP/BC/03/M	Cobas c503	x	
Lipoprotein (a)	Serum, Heparin Plasma, EDTA Plasma	Turbidimetry	SOP/BC/03/M	Cobas c503	x	
Rheumatoid Factor	Serum, Heparin Plasma, EDTA Plasma	Turbidimetry	SOP/BC/03/M	Cobas c503	x	
Total Protein/Creatinine Ratio	Urine	Calculation	SOP/BC/02/L	Cobas c503	x	
Transferrin	Serum, Heparin Plasma	Turbidimetry	SOP/BC/03/M	Cobas c503	x	

Type of Test:
Spectrometry/ reflectrometry*

Analyte (measurement parameter)	Test material (matrix)	Test technique	Procedure / Version	Instrument	CE Kit	Date of New/Changed/ Deleted Parameters
Specific gravity (stix)	Urine	Reflectrometry, carrier based examination procedures.	SOP/U/01/B	Cobas u411	x	
Leucocytes (stix)	Urine	Reflectrometry, carrier based examination procedures.	SOP/U/01/B	Cobas u411	x	
Nitrite (stix)	Urine	Reflectrometry, carrier based examination procedures.	SOP/U/01/B	Cobas u411	x	
pH (stix)	Urine	Reflectrometry, carrier based examination procedures.	SOP/U/01/B	Cobas u411	x	
Protein (stix)	Urine	Reflectrometry, carrier based examination procedures.	SOP/U/01/B	Cobas u411	x	
Glucose (stix)	Urine	Reflectrometry, carrier based examination procedures.	SOP/U/01/B	Cobas u411	x	
Ketone bodies (stix)	Urine	Reflectrometry, carrier based examination procedures.	SOP/U/01/B	Cobas u411	x	
Urobilinogen (stix)	Urine	Reflectrometry, carrier based examination procedures.	SOP/U/01/B	Cobas u411	x	
Bilirubin (stix)	Urine	Reflectrometry, carrier based examination procedures.	SOP/U/01/B	Cobas u411	x	
Red blood cells (stix)	Urine	Reflectrometry, carrier based examination procedures.	SOP/U/01/B	Cobas u411	x	

Medicinal Analytical field: Immunology
Type of test:
Ligand assays*

Analyte (measurement parameter)	Test material (matrix)	Test technique	Procedure/Version	Instrument	CE Kit	Date of New/Changed/ Deleted Parameters
ANA Profile	Serum	Immunoblot	SOP/AI/03/I	Blue Diver	x	

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Anti-TG	Serum, EDTA Plasma	ECLIA	SOP/IM/04/J	Cobas e801	x	
Anti-TPO	Serum, Heparin Plasma, EDTA Plasma	ECLIA	SOP/IM/04/J	Cobas e801	x	
Atopy Allergy Screening	Serum	Immunoblot	SOP/AI/08/H	Euroblot 1	x	
Cardiolipin IgG	Serum	EIA	SOP/AI/05/I	Euroimmun Analyzer I 2P	x	
Cardiolipin IgM	Serum	EIA	SOP/AI/05/I	Euroimmun Analyzer I 2P	x	
CCP Abs	Serum	EIA	SOP/AI/02/I	Euroimmun Analyzer I 2P	x	
dsDNA/Nucleosomes Abs	Serum	EIA	SOP/AI/01/I	Euroimmun Analyzer I 2P	x	
Food Allergy Screening	Serum	Immunoblot	SOP/AI/08/H	Euroblot 1	x	
IgE, total	Serum, Heparin Plasma, EDTA Plasma	ECLIA	SOP/IM/11/J	Cobas e801	x	
Phospholipid IgG	Serum	EIA	SOP/AI/10/A	Virclia lotus	x	
Phospholipid IgM	Serum	EIA	SOP/AI/10/A	Virclia lotus	x	
Respiratory Allergy Screening	Serum	Immunoblot	SOP/AI/08/H	Euroblot 1	x	
Rheumatoid Factor IgG	Serum	EIA	SOP/AI/11/A	Euroimmun Analyzer I 2P	x	03.12.2024
Rheumatoid Factor IgM	Serum	EIA	SOP/AI/11/A	Euroimmun Analyzer I 2P	x	03.12.2024
Rheumatoid Factor IgA	Serum	EIA	SOP/AI/11/A	Euroimmun Analyzer I 2P	x	03.12.2024
Tissue Transglutaminase IgA	Serum	EIA	SOP/AI/09/F	Euroimmun Analyzer I 2P	x	
Tissue Transglutaminase IgG	Serum	EIA	SOP/AI/09/F	Euroimmun Analyzer I 2P	x	

Type of Test:

Microscopy*

Analyte (measurement parameter)	Test material (matrix)	Test technique	Procedure/Version	Instrument	CE Kit	Date of New/Changed/Deleted Parameters
AMA/LKM	Serum	IFT	SOP/AI/06/L	IF Sprinter /Manual	x	
ANA/ASMA type Actin	Serum	IFT	SOP/AI/06/L	IF Sprinter /Manual	x	
ANCA (cANCA, pANCA)	Serum	IFT	SOP/AI/06/L	IF Sprinter /Manual	x	
Endomysium IgA	Serum	IFT	SOP/AI/06/L	IF Sprinter /Manual	x	
Endomysium IgG	Serum	IFT	SOP/AI/06/L	IF Sprinter /Manual	x	
Gliadin IgA	Serum	IFT	SOP/AI/06/L	IF Sprinter /Manual	x	

Type of Test:

Spectrometry (Turbidimetry)*

Analyte (measurement parameter)	Test material (matrix)	Test technique	Procedure/Version	Instrument	CE Kit	Date of New/Changed/Deleted Parameters
Complement C3c	Serum, Heparin Plasma	Turbidimetry	SOP/BC/03/M	Cobas c503	x	
Complement C4	Serum, Heparin Plasma, EDTA Plasma	Turbidimetry	SOP/BC/03/M	Cobas c503	x	
Immunoglobulin A (IgA)	Serum, Heparin Plasma, EDTA Plasma	Turbidimetry	SOP/BC/03/M	Cobas c503	x	
Immunoglobulin G (IgG)	Serum, Heparin Plasma, EDTA Plasma	Turbidimetry	SOP/BC/03/M	Cobas c503	x	
Immunoglobulin M (IgM)	Serum, Heparin Plasma, EDTA Plasma	Turbidimetry	SOP/BC/03/M	Cobas c503	x	

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Medicinal Analytical field: Humangenetics (Molecular Genetics)
Type of test:
Molecular Biological Test techniques (Amplification Test technique)

Analyte (measurement parameter)	Test material (Sample material; Testmaterial)	Test technique	Procedure/Version	Instrument	CE Kit	Date of New/Changed/ Deleted Parameters
HLA-B27	EDTA blood; DNA	PCR Microarray	SOP.PCR.11 A	EUROArray Scanner		
Factor V	EDTA blood; DNA	PCR Microarray	SOP.PCR.12 A	EUROArray Scanner		
Factor II	EDTA blood; DNA	PCR Microarray	SOP.PCR.12 A	EUROArray Scanner		
MTHFR	EDTA blood; DNA	PCR Microarray	SOP.PCR.12 A	EUROArray Scanner		

Medicinal Analytical field: Microbiology
Type of test:
Agglutination

Analyte (measurement parameter)	Test material (matrix)	Test technique	Procedure/Version	Instrument	CE Kit	Date of New/Changed/ Deleted Parameters
Streptococci	Culture	Agglutination	SOP/M/06/B	Manual	x	
TPHA	Serum	Agglutination	SOP/SE/05/F	Manual	x	

Type of test:
Cell Function Tests

Analyte (measurement parameter)	Test material (matrix)	Test technique	Procedure/Version	Instrument	CE Kit	Date of New/Changed/ Deleted Parameters
Interferon gamma Stimulation test (for indirect testing of Mycobacter tuberculosis)	EDTA Blood	CLIA	SOP.SE.14 A	Diasorin	x	

Type of test:
Ligand assays*

Analyte (measurement parameter)	Test material (matrix)	Test technique	Procedure/Version	Instrument	CE Kit	Date of New/Changed/ Deleted Parameters
Mycoplasma pneumoniae IgA	Serum	EIA	SOP/SE/15/A	Euroimmun Analyzer I 2P	x	
Mycoplasma pneumoniae IgG	Serum	EIA	SOP/SE/15/A	Euroimmun Analyzer I 2P	x	
Mycoplasma pneumoniae IgM	Serum	EIA	SOP/SE/18/A	Virclia lotus	x	
Toxoplasma IgG	Serum, Heparin Plasma, EDTA Plasma	ECLIA	SOP/IM/14/K	Cobas e801	x	
Toxoplasma IgM	Serum, Heparin Plasma, EDTA Plasma	ECLIA	SOP/IM/14/K	Cobas e801	x	

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Type of test:						
Chromatography (Immunochromography)*						
Analyte (measurement parameter)	Test material (matrix)	Test technique	Procedure/Version	Instrument	CE Kit	Date of New/Changed/Deleted Parameters
Helicobacter Pylori Ag	Stool	Immunochromatography	SOP/M/11/A	Manual	x	

Type of test:						
Culture Examinations						
Analyte (measurement parameter)	Test material (matrix)	Test technique	Procedure/Version	Instrument	CE Kit	Date of New/Changed/Deleted Parameters
Aerobic Bacteria	Culture	Culture	SOP/M/01/D-08/D	Manual	x	
Anaerobic Bacteria	Culture	Culture	SOP/M/02/E-04/F	Manual	x	
Corynebacterium species	Culture	Culture	SOP/M/01/D-08/D	Manual	x	
Enterobacteriaceae	Culture	Culture	SOP/M/01/D-08/D	Manual	x	
Gardnerella vaginalis	Culture	Culture	SOP/M/01/D-08/D	Manual	x	
Haemophilus	Culture	Culture	SOP/M/03/E-08/D	Manual	x	
Lactobacillus	Culture	Culture	SOP/M/01/D-08/D	Manual	x	
MRSA	Culture	Culture	SOP/M/01/D-08/D	Manual	x	
Neisseria gonorrhoeae	Culture	Culture	SOP/M/01/D-08/D	Manual	x	
Non-fermenter	Culture	Culture	SOP/M/01/D-08/D	Manual	x	
Staphylococci	Culture	Culture	SOP/M/01/D-08/D	Manual	x	
Streptococci	Culture	Culture	SOP/M/01/D-08/D	Manual	x	
Yeast (Candida)	Culture	Culture	SOP/M/01/D-08/D	Manual	x	
Aerobic Bacteria	Urine, Genital Tract Test material (matrix), Body fluids, Deep wound, Pus, Abscess, Stool, Throat swab, Nasal swab, Ear swab, Eye swab, Skin swab, Sputum	Culture	SOP/M/01/D-08/D	Manual	x	
Anaerobic Bacteria	Genital Tract Test material (matrix), Body fluids, Deep wound, Pus, Abscess	Culture	SOP/M/02/E-04/F	Manual	x	
Campylobacter, Salmonella, Shigella	Stool	Culture	SOP/M/05/E	Manual	x	

Type of test:						
Bacterial Susceptibility testing*						
Analyte (measurement parameter)	Test material (matrix)	Test technique	Procedure/Version	Instrument	CE Kit	Date of New/Changed/Deleted Parameters
Aerobic Bacteria	Culture	Disc diffusion test	SOP/M/09/E	Manual	x	
Anaerobic Bacteria	Culture	Disc diffusion test	SOP/M/09/E	Manual	x	

Type of test:						
Microbial differentiation/Identification/Typing*						

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Analyte (measurement parameter)	Test material (matrix)	Test technique	Procedure/Version	Instrument	CE Kit	Date of New/Changed/Deleted Parameters
Aerobic Bacteria	Culture	Biochemical	SOP/M/01/D-08/D	Manual	X	
Anaerobic Bacteria	Culture	Biochemical	SOP/M/02/E-04/F	Manual	X	
Corynebacterium species	Culture	Biochemical	SOP/M/01/D-08/D	Manual	X	
Enterobacteriaceae	Culture	Biochemical	SOP/M/01/D-08/D	Manual	X	
Gardnerella vaginalis	Culture	Biochemical	SOP/M/01/D-08/D	Manual	X	
Haemophilus	Culture	Biochemical	SOP/M/03/E-08/D	Manual	X	
Lactobacillus	Culture	Biochemical	SOP/M/01/D-08/D	Manual	X	
MRSA	Culture	Biochemical	SOP/M/01/D-08/D	Manual	X	
Neisseria gonorrhoeae	Culture	Biochemical	SOP/M/01/D-08/D	Manual	X	
Non-fermenter	Culture	Biochemical	SOP/M/01/D-08/D	Manual	X	
Staphylococci	Culture	Biochemical	SOP/M/01/D-08/D	Manual	X	
Streptococci	Culture	Biochemical	SOP/M/01/D-08/D	Manual	X	
Yeast (Candida)	Culture	Biochemical	SOP/M/01/D-08/D	Manual	X	

Type of test:
Microscopy*

Analyte (measurement parameter)	Test material (matrix)	Test technique	Procedure/Version	Instrument	CE Kit	Date of New/Changed/Deleted Parameters
Aerobic Bacteria	Culture	Microscopy	SOP/M/01/D-08/D	Manual	X	
Anaerobic Bacteria	Culture	Microscopy	SOP/M/02/E-04/F	Manual	X	
Corynebacterium species	Culture	Microscopy	SOP/M/01/D-08/D	Manual	X	
Enterobacteriaceae	Culture	Microscopy	SOP/M/01/D-08/D	Manual	X	
Gardnerella vaginalis	Culture	Microscopy	SOP/M/01/D-08/D	Manual	X	
Haemophilus	Culture	Microscopy	SOP/M/03/E-08/D	Manual	X	
Lactobacillus	Culture	Microscopy	SOP/M/01/D-08/D	Manual	X	
MRSA	Culture	Microscopy	SOP/M/01/D-08/D	Manual	X	
Neisseria gonorrhoeae	Culture	Microscopy	SOP/M/01/D-08/D	Manual	X	
Non-fermenter	Culture	Microscopy	SOP/M/01/D-08/D	Manual	X	
Staphylococci	Culture	Microscopy	SOP/M/01/D-08/D	Manual	X	
Streptococci	Culture	Microscopy	SOP/M/01/D-08/D	Manual	X	
Yeast (Candida)	Culture	Microscopy	SOP/M/01/D-08/D	Manual	X	

Type of Test:
Molecular Biological Test techniques (Amplification Test technique)*

Analyte (measurement parameter)	Test material (matrix)	Test technique	Procedure/Version	Instrument	CE Kit	Date of New/Changed/Deleted Parameters
Chlamydia trachomatis	Thinprep, swab, urine, seminal fluid	multiplex real-time PCR assay	SOP/PCR/10/C	Nimbus- Hamilton (Seegene)/CFX96 (Biorad)	X	
Neisseria gonorrhoeae	Thinprep, swab, urine, seminal fluid	multiplex real-time PCR assay	SOP/PCR/10/C	Nimbus- Hamilton (Seegene)/CFX96 (Biorad)	X	
Mycoplasma genitalium	Thinprep, swab, urine, seminal fluid	multiplex real-time PCR assay	SOP/PCR/10/C	Nimbus- Hamilton (Seegene)/CFX96 (Biorad)	X	

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Mycoplasma hominis	Thinprep, swab, urine	multiplex real-time PCR assay	SOP/PCR/10/C	Nimbus- Hamilton (Seegene)/CFX96 (Biorad)	x	
Treponema pallidum	Thinprep, swab, urine	multiplex real-time PCR assay	SOP/PCR/10/C	Nimbus- Hamilton (Seegene)/CFX96 (Biorad)	x	
Trichomonas vaginalis	Thinprep, swab, urine, seminal fluid	multiplex real-time PCR assay	SOP/PCR/10/C	Nimbus- Hamilton (Seegene)/CFX96 (Biorad)	x	
Ureaplasma parvum	Thinprep, swab, urine	multiplex real-time PCR assay	SOP/PCR/10/C	Nimbus- Hamilton (Seegene)/CFX96 (Biorad)	x	
Ureaplasma urealyticum	Thinprep, swab, urine	multiplex real-time PCR assay	SOP/PCR/10/C	Nimbus- Hamilton (Seegene)/CFX96 (Biorad)	x	

Medicinal Analytical field: Virology
Type of test:
Ligand Assays*

Analyte (measurement parameter)	Test material (matrix)	Test technique	Procedure/Version	Instrument	CE Kit	Date of New/Changed/ Deleted Parameters
Anti-HBe	Serum, Heparin Plasma, EDTA Plasma	ECLIA	SOP/IM/07/L	Cobas e411	x	
Anti-HAV	Serum, Heparin Plasma, EDTA Plasma	ECLIA	SOP/IM/08/K	Cobas e411	x	
Anti-HAV IgM	Serum, Heparin Plasma, EDTA Plasma	ECLIA	SOP/IM/08/K	Cobas e411	x	
Anti-HBc	Serum, Heparin Plasma, EDTA Plasma	ECLIA	SOP/IM/07/L	Cobas e411	x	
Anti-HBs	Serum, EDTA Plasma	ECLIA	SOP/IM/07/L	Cobas e411	x	
CMV Abs IgG	Serum, Heparin Plasma, EDTA Plasma	ECLIA	SOP/IM/20/M	Cobas e801	x	
CMV ABS IgM	Serum, Heparin Plasma, EDTA Plasma	ECLIA	SOP/IM/20/M	Cobas e801	x	
HBe Ag	Serum, Heparin Plasma, EDTA Plasma	ECLIA	SOP/IM/07/L	Cobas e411	x	
HBs Ag	Serum, Heparin Plasma, EDTA Plasma	ECLIA	SOP/IM/07/L	Cobas e411	x	
HCV Abs	Serum, Heparin Plasma, EDTA Plasma	ECLIA	SOP/IM/16/J	Cobas e801	x	
HIV combi	Serum, Heparin Plasma, EDTA Plasma	ECLIA	SOP/IM/09/J	Cobas e801	x	
HSV 1 IgG	Serum	EIA	SOP/SE/15/A	Euroimmun Analyzer I 2P	x	
HSV 1 IgM	Serum	EIA	SOP/SE/18/A	VirCia Lotus	x	
HSV 2 IgG	Serum	EIA	SOP/SE/15/A	Euroimmun Analyzer I 2P	x	
HSV 2 IgM	Serum	EIA	SOP/SE/18/A	VirCia Lotus	x	
Measles IgG	Serum	CLIA	SOP.SE.17 A	Diasorin	x	
Mumps IgG	Serum	CLIA	SOP.SE.17 A	Diasorin	x	

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Rubella IgG	Serum, Heparin Plasma, EDTA Plasma	ECLIA	SOP/IM/14/K	Cobas e801	x	
Rubella IgM	Serum, Heparin Plasma, EDTA Plasma	ECLIA	SOP/IM/14/K	Cobas e801	x	
Varicella Zooster Virus (VZV) IgG	Serum	CLIA	SOP.SE.17 A	Diasorin	x	

Type of Test:
Microscopy*

Analyte (measurement parameter)	Test material (matrix)	Test technique	Procedure/Version	Instrument	CE Kit	Date of New/Changed/Deleted Parameters
EBNA	Serum	IFT	SOP/SE/02/H	Microscope, manual	x	
EBV-CA-IgG	Serum	IFT	SOP/SE/02/H	Microscope, manual	x	
EBV-CA-IgM	Serum	IFT	SOP/SE/02/H	Microscope, manual	x	
EBV-EA-IgG	Serum	IFT	SOP/SE/02/H	Microscope, manual	x	

Type of Test:
Molecular Biological Test techniques *

Analyte (measurement parameter)	Test material (matrix)	Test technique	Procedure/Version	Instrument	CE Kit	Date of New/Changed/Deleted Parameters
CMV DNA	Thinprep, swab, urine	multiplex real-time PCR assay	SOP/PCR/10/C	Nimbus- Hamilton (Seegene)/CFX96 (Biorad)	x	
HPV	LBC, Swab	Real-Time PCR	SOP/PCR/09/B	Nimbus- Hamilton (Seegene)/CFX96 (Biorad)	x	
HSV1 DNA	Thinprep, swab, urine	multiplex real-time PCR assay	SOP/PCR/10/C	Nimbus- Hamilton (Seegene)/CFX96 (Biorad)	x	
HSV2 DNA	Thinprep, swab, urine	multiplex real-time PCR assay	SOP/PCR/10/C	Nimbus- Hamilton (Seegene)/CFX96 (Biorad)	x	
Sars-CoV-2 RNA	Swab	Real-Time PCR	SOP/PCR/17/A	Nimbus- Hamilton (Seegene)/CFX96 (Biorad)	x	

Medicinal Analytical field: Transfusion Medicine
Type of test:
Agglutination*

Analyte (measurement parameter)	Test material (matrix)	Test technique	Procedure/Version	Instrument	CE Kit	Date of New/Changed/Deleted Parameters
ABO/Rh Blood Group + Reverse Grouping	EDTA Blood, Serum	Agglutination	SOP/HE/09/B	BioRad	x	
Coombs Test, direct	EDTA Blood	Agglutination	SOP/HE/10/A	BioRad	x	
Coombs Test, indirect	Serum, EDTA Plasma	Agglutination	SOP/HE/10/A	BioRad	x	
Rh Subgroups and Kell	EDTA Blood	Agglutination	SOP/HE/09/B	BioRad	x	