

### Scope of accreditation

Accredited as Testing laboratory according to ISO15189

Landspítali - National University Hospital, Department of Clinical Microbiology, Reykjavik - **10446**

Method	System	Test method	Equipment	Qualitative/Quantitative
<b>Virology</b>				
<b>Human Immunodeficiency Virus</b>				
HIV combi PT	Serum/plasma	CLIA test	Cobas e411	Qualitative
HIV Duo	Serum/plasma	CLIA test	Cobas 801	Qualitative
Murex HIV ig/Ab confirmatory test	Serum/plasma	ELISA	Multiscan Ex	Qualitative
INNO-LIA HIV I/II confirmatory test	Serum/plasma	Line Immuno Assay		Qualitative
HIV-1	Plasma	PCR	Cobas 8800	Qualitative/Quantitative (cp/ml)
<b>Hepatitis A virus</b>				
HAV total	Serum/plasma	CLIA test	Cobas e411	Qualitative
HAV IgM	Serum/plasma	CLIA test	Cobas e411	Qualitative
Anti-HAV II	Serum/plasma	CLIA test	Cobas 801	Qualitative
<b>Hepatitis B virus</b>				
Anti HBc IgM	Serum/plasma	CLIA test	Cobas e411	Qualitative
Anti HBe	Serum/plasma	CLIA test	Cobas e411	Qualitative
Anti HBs	Serum/plasma	CLIA test	Cobas e411	Qualitative/Quantitative (IU/l)
Anti HBs II	Serum/plasma	CLIA test	Cobas 801	Qualitative/Quantitative (IU/l)
Anti-HBc II	Serum/plasma	CLIA test	Cobas 801	Qualitative
HBeAg	Serum/plasma	CLIA test	Cobas e411	Qualitative
HBsAg II	Serum/plasma	CLIA test	Cobas e411, Cobas 801	Qualitative
Monolisa HBsAg confirmatory test	Serum/plasma	ELISA	Multiscan Ex	Qualitative

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HBV	Serum/plasma	PCR	Cobas 8800	Qualitative/Quantitative (IU/ml)
<b>Hepatitis C virus</b>				
Anti HCV II	Serum/plasma	CLIA test	Cobas e411, Cobas 801	Qualitative
Ortho HCV 3.0	Serum/plasma	ELISA	Multiscan Ex	Qualitative
INNO-LIA HCV confirmatory test	Serum/plasma	Line Immuno Assay		Qualitative
HCV	Serum/plasma	PCR	Cobas 8800	Qualitative/Quantitative (IU/ml)
<b>Cytomegalovirus</b>				
CMV IgM	Serum/plasma	CLIA test	Cobas e411, Cobas 801	Qualitative
CMV IgG	Serum/plasma	CLIA test	Cobas e411, Cobas 801	Qualitative
<b>Herpes Simplex virus</b>				
HSV-1 IgG	Serum/plasma	CLIA test	Cobas e411	Qualitative
HSV-2 IgG	Serum/plasma	CLIA test	Cobas e411	Qualitative
<b>Rubella virus</b>				
Rubella IgG	Serum/plasma	CLIA test	Cobas e411, Cobas 801	Qualitative/Quantitative (IU/ml)
<b>Syphilis</b>				
Syphilis	Serum/plasma	CLIA test	Cobas e411, Cobas 801	Qualitative
<b>SARS-CoV 2</b>				
SARS-CoV 2	Serum/plasma	PCR	AB-7500	
SARS-CoV 2 RNA	Serum/plasma	PCR	Cobas 8800	

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Anti-SARS-CoV 2	Serum/plasma	CLIA test	Cobas 801	Qualitative
Anti-SARS-CoV 2 S	Serum/plasma	CLIA test	Cobas 801	Qualitative
<b>Bacteriology</b>				
Bacteria, pathogens	Blood	Aerob, anaerob culture, microscopy (Grams)	BactAlert, Aerospray, microscope, Maldi-Tof	Qualitative
Bacteria, pathogens	Pleural fluid	Aerob, anaerob culture, microscopy (Grams)	BactAlert, Aerospray, microscope, Maldi-Tof	Qualitative
Bacteria, pathogens	Throat	Aerob, anaerob culture	Maldi-Tof	Qualitative
Bacteria, pathogens	Abscesses	Aerob, anaerob culture, microscopy (Grams)	Aerospray, microscope, Maldi-Tof	Qualitative
Bacteria, pathogens	Female genitals	Aerob, anaerob culture, microscopy (Grams)	Aerospray, microscope, Maldi-Tof	Qualitative
Bacteria, pathogens	Spinal fluid, joint fluid and bursa fluid	Aerob, anaerob culture, microscopy (Grams)	BactAlert, Aerospray, microscope, Maldi-Tof	Qualitative
Bacteria, pathogens	Lower respiratory tract	Aerob, anaerob culture, microscopy (Grams)	Aerospray, microscope, Maldi-Tof	Qualitative
Bacteria, pathogens	Wounds	Aerob, anaerob culture	Maldi-Tof	Qualitative
Bacteria, pathogens	Urine	Aerob culture, microscopy (direct)	Microscope, Maldi-Tof	Semiquantitative CFU/L

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<i>Campylobacter</i>	Faeces	Microaerophil culture	Maldi-Tof	Qualitative
<i>Chlamydia trachomatis</i>	Urine and female genitals	Molecular testing	Cobas 4800	Qualitative
EHEC	Faeces, rectum and culture of bacteria	Aerob culture, E.coli O157 agglutination, PCR	Maldi-Tof, AB 7500	Qualitative
ESBL	Faeces, rectum and culture of bacteria	Aerob culture, ESBL disk diffusion, PCR	Maldi-Tof, BD Max	Qualitative
KPC	Faeces, rectum and culture of bacteria	Aerob culture, KPC disk diffusion, PCR	Maldi-Tof, BD Max	Qualitative
MRSA	Throat-, nose- and perineum	Aerob culture, PCR	Maldi-Tof, BD Max	Qualitative
<i>Neisseria gonorrhoeae</i>	Urine and female genitals	Molecular testing	Cobas 4800	Qualitative
Susceptibility testing	Culture of bacteria	Disk diffusion on Muller Hinton agar, EUCAST method		SIR
Susceptibility testing	Culture of bacteria	Disk diffusion on Muller Hinton + NAD agar, EUCAST method		SIR
Susceptibility testing	Culture of bacteria	AmpC disk diffusion		

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<i>Salmonella sp.</i>	Faeces	Aerob culture, salmonella antisera	Maldi-Tof	Qualitative
<i>Shigella sp.</i>	Faeces	Aerob culture, Shigella antisera	Maldi-Tof	Qualitative
<i>S. Agalactiae</i> (GBS)	Female genitals	Aerob culture	Maldi-Tof	Qualitative
VRE	Faeces, rectum and culture of bacteria	Aerob culture, PCR	Maldi-Tof, BD Max	Qualitative
<b>Mycology</b>				
Fungi	Blood	Aerob culture, microscopy (Grams)	BactAlert, Aerospray, microscope, Maldi-Tof	Qualitative
Fungi	Pleural fluid	Aerob culture, microscopy (Grams)	BactAlert, Aerospray, microscope, Maldi-Tof	Qualitative
Fungi	Throat	Aerob culture	Maldi-Tof	Qualitative
Fungi	Abscesses	Aerob culture, microscopy (Grams)	Aerospray, microscope, Maldi-Tof	Qualitative
Fungi	Female genitals	Aerob culture, microscopy (Grams)	Aerospray, microscope, Maldi-Tof	Qualitative
Fungi	Spinal fluid, joint fluid and bursa	Aerob culture, microscopy (Grams)	BactAlert, Aerospray, microscope, Maldi-Tof	Qualitative

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	fluid			
Fungi	Lower respiratory tract	Aerob culture, microscopy (Grams)	Aerospray, microscope, Maldi-Tof	Qualitative
Fungi	Wounds	Aerob culture, microscopy (Grams)	Aerospray, microscope, Maldi-Tof	Qualitative
Fungi	Urine	Aerob culture, microscopy (Grams and direct)	Aerospray, microscope, Maldi-Tof	Semiquantitative CFU/L
Species identification	Culture of bacteria and fungi	Mass spectrometry	Maldi-Tof	Qualitative

The accreditation does not cover sampling activities. If the laboratory, regardless of this, performs the sampling by itself, then the testing is not considered to be performed under accreditation.

Activities outside the laboratory's own premises, so-called field activities, are not included in the accreditation.