



EA MLA Signatory Český institut pro akreditaci, o.p.s. (Czech Accreditation Institute) Hájkova 2747/22, Žižkov, 130 00 Praha 3

issues

according to section 16 of Act No. 22/1997 Coll., on technical requirements for products and on changes and amendments to some Acts, as amended

CERTIFICATE OF ACCREDITATION

No. 414/2025

Ústřední vojenská nemocnice - Vojenská fakultní nemocnice Praha with registered office U Vojenské nemocnice 1200/1, 169 02 Praha 6 Company Registration No. 61383082

for the Medical Laboratory No. **8195** Clinical Laboratories

Scope of accreditation:

Examinations in the field of clinical biochemistry, medical microbiology, haematology, immunohaematology and transfusion service, including shared examinations and sampling of venous and capillary blood to the extent as specified in the appendix to this Certificate.

This Certificate of Accreditation is a proof of accreditation issued on the basis of assessment of fulfillment of the accreditation criteria in accordance with

ČSN EN ISO 15189 ed. 3:2023

In its activities performed within the scope and for the period of validity of this Certificate, the abovementioned Accredited Body is entitled to refer to this Certificate, provided that the accreditation is not suspended and the Accredited Body meets the specified accreditation requirements in accordance with the relevant regulations applicable to the activity of an accredited conformity assessment body.

This Certificate of Accreditation replaces, to the full extent, Certificate No.: 350/2024 of 18/07/2024, and/or any administrative acts building upon it.

The Certificate of Accreditation is valid until: 01/08/2030

Prague: 01/08/2025





Signed in the Czech original: Milena Lochmanová on 01/08/2025

Milena Lochmanová
Director of the Department
of Medical Laboratories
Czech Accreditation Institute

This translation of the Czech original has been issued by: Jana Chvalovská

Accredited entity according to ČSN EN ISO 15189 ed. 3:2023:

Ústřední vojenská nemocnice - Vojenská fakultní nemocnice Praha

CAB Number 8195, Clinical Laboratories U Vojenské nemocnice 1200/1, 169 02 Praha 6

The laboratory applies a flexible approach to the scope of accreditation.

The current "List of activities within the flexible scope" is available on the website https://www.uvn.cz/cs/laboratorni-prirucky-a-referencni-rozmezi-laboratori

Examinations:

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹			
	222 - Transfusion Medicine							
1.	Blood type	Agglutination in test tubes (manual)	Commercial procedure	Blood	A, B			
2.	Blood type	Agglutination in microplates	Commercial procedure	Blood	A, B			
3.	Screening of anti- erythrocyte antibodies	Solid phase	Commercial procedure	Serum, plasma	A, B			
4.	Screening of anti- erythrocyte antibodies	Gel column agglutination (manual)	Commercial procedure	Serum, plasma	A, B			
5.	Examination of compatibility	Electronic crossmatch	Commercial procedure	Blood	A, B			
6.	Examination of compatibility	Gel column agglutination (manual)	Commercial procedure	Blood	A, B			
7.	Examination of compatibility	Solid phase	Commercial procedure	Blood	A, B			
8.	Identification of anti- erythrocyte antibodies	Gel column agglutination (manual)	Commercial procedure	Serum, plasma	A, B			
9.	Identification of anti- erythrocyte antibodies	Solid phase	Commercial procedure	Serum, plasma	A, B			
10.	Direct antiglobulin test	Gel column agglutination	Commercial procedure	Blood	A, B			
		(manual)						

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Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹			
	801 – Clinical Biochemistry							
1.	Minerals	Potentiometry	Commercial procedure	Serum	A, B			
2.	Enzymes	Absorption spectrophotometry	Commercial procedure	Serum	A, B, C			
3.	Glucose	Absorption spectrophotometry	Commercial procedure	Serum, plasma	A, B			
4.	Tumor markers	Immunoassay with luminometric detection	Commercial procedure	Serum	A, B, C			
5.	Proteins	Absorption spectrophotometry	Commercial procedure	Serum	A, B			
6.	Lipids	Absorption spectrophotometry	Commercial procedure	Serum	A, B			
7.	Non-protein nitrogenous compounds	Absorption spectrophotometry	Commercial procedure	Serum	A, B			
8.	Glycated haemoglobin	High-Performance Liquid Chromatography	Commercial procedure	Blood	A, B			
9.	Cardiac markers	Immunoassay with luminometric detection	Commercial procedure	Serum	A, B			
10.	Total bilirubin	Absorption spectrophotometry	Commercial procedure	Serum	A, B			
11.	Acid-base balance	Potentiometry; Amperometry	Commercial procedure	Blood	A, B			
12.	Vitamins	Immunoassay with luminometric detection	Commercial procedure	Serum	A, B, C			

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Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
		802 – Medical Mi	crobiology		l.
1.	Microbiological examination of clinical material	Microscopy; Aerobic culture; Anaerobic culture	Published procedure	Clinical material	A, B, D
2.	Microbiological examination of clinical material	Aerobic culture	Published procedure	Clinical material	A, B, D
3.	Microbiological examination of primarily sterile material	Microscopy; Aerobic culture; Anaerobic culture	Published procedure	Liquid clinical material	A, B, D
4.	Microbiological examination of foreign bodies	Aerobic culture; Anaerobic culture	Published procedure	Foreign bodies	A, B, D
5.	Microbiological examination of urogenital tract	Microscopy; Aerobic culture	Published procedure	Genitourinary system material	A, B, D
6.	Qualitative antibiotic susceptibility testing	Disk diffusion test	Published procedure	Bacterial culture, yeast culture	A, B
7.	Quantitative antibiotic susceptibility testing	Gradient diffusion method	Published procedure	Bacterial culture, yeast culture	A, B
8.	Quantitative antibiotic susceptibility testing	Microdilution method (automated)	Commercial procedure	Bacterial culture, yeast culture	A, B
9.	Microbiological examination of the lower respiratory tract	Microscopy; Aerobic culture	Published procedure	Material from lower respiratory tract	A, B, D
10.	Antigens of infectious agents	Immunochromatography	Commercial procedure	Urine, stool	A, B, C
11.	Microbiological examination of upper respiratory tract	Aerobic culture	Published procedure	Material from upper respiratory tract	A, B, D

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Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
12.	Microbiological examination of blood and primarily sterile body fluids	Aerobic culture; Anaerobic culture; (automated)	Commercial procedure Published procedure	Liquid clinical material	A, B, D
13.	Identification of the microorganism	Phenotyping	Commercial procedure	Bacterial culture, yeast culture	A, B
14.	Identification of the microorganism	Mass spectrometry	Commercial procedure	Bacterial culture, yeast culture	A, B, C
15.	Quantitative microbiological examination of urine	Aerobic culture	Published procedure	Urine	A, B
16.	Microbiological examination of rectal swab and stool	Aerobic culture; Anaerobic culture	Published procedure	Rectal swab, stool	A, B
17.	Identification of bacteria	Agglutination	Commercial procedure	Bacterial culture	A, B
18.	Antibodies against infectious agents	Immunoassay with luminometric detection	Commercial procedure	Body fluids	A, B, C, D
19.	Antibodies against infectious agents	Immunoassay with photometric detection	Commercial procedure	Body fluids	A, B, C, D
20.	Antibodies against infectious agents	Immunoblotting	Commercial procedure	Body fluids	A, B, C, D
21.	Antigens of infectious agents	Immunoassay with luminometric detection	Commercial procedure	Serum	A, B, C
22.	HIV markers	Immunoassay with luminometric detection	Commercial procedure	Serum	A, B
23.	Antigens of infectious agents	Immunoassay with luminometric detection	Commercial procedure	Serum	A, B, C
24.	Detection of nucleic acids of infectious agents	Real-Time PCR	Commercial procedure	Clinical material	A, B, C, D

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Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
25.	Detection of nucleic acids of infectious agents	Real-Time PCR (automated)	Commercial procedure	Blood	A, B, C
26.	Detection of nucleic acids of infectious agents	RT Real-Time PCR (automated)	Commercial procedure	Clinical material	A, B, C, D
27.	Detection of nucleic acids of infectious agents	RT Real-Time PCR	Commercial procedure	Clinical material	A, B, C, D
		813 - Allergology and Imm	unology Laboratory		
1.	C-reactive protein (CRP)	Immunoturbidimetry	Commercial procedure	Serum	A, B
		815 - Nuclear Medici	ne Laboratory		
1.	Hormones	Immunoassay with luminometric detection	Commercial procedure	Serum	A, B, C
2.	Tumour markers	Immunoassay with luminometric detection	Commercial procedure	Serum	A, B, C
3.	Myoglobin	Immunoassay with luminometric detection	Commercial procedure	Serum	A, B
		818 - Haematology	Laboratory		
1.	Blood count with a five-part differential leukocyte count	Flow cytometry; Impedance method; Photometry; Calculations	Commercial procedure	Blood	A, B
2.	Activated partial thromboplastin time	Coagulation method with optical detection of coagulum; Calculations	Commercial procedure	Plasma	A, B
3.	Prothrombin test	Coagulation method with optical detection of coagulum; Calculations	Commercial procedure	Plasma	A, B

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Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
4.	Reticulocytes	Flow cytometry; Impedance method; Calculations	Commercial procedure	Blood	A, B
5.	Peripheral blood smear test	Microscopy	Published procedure	Blood	A, B
6.	Peripheral blood smear test	Digital microscopy	Commercial procedure	Blood	A, B
7.	Fibrinogen	Coagulation method with optical detection of coagulum	Commercial procedure	Plasma	A, B
8.	Antithrombin	Chromogenic method	Commercial procedure	Plasma	A, B
9.	Factor VIII	Coagulation method with optical detection of coagulum	Commercial procedure	Plasma	A, B
10.	D-dimers	Immunoturbidimetry	Commercial procedure	Plasma	A, B
11.	Anti–Xa activity	Chromogenic method	Commercial procedure	Plasma	A, B
12.	Thrombin test	Coagulation method with optical detection of coagulum; Calculations	Commercial procedure	Plasma	A, B
13.	Detection of HIT- associated antibodies	Immunoturbidimetry	Commercial procedure	Plasma	A, B

Primary sample collection:

Ordinal Number	Sample collection technique	Identification of sample collection procedure	Collected material	Degrees od freedom ¹
1.	Venepuncture	Published procedure	Venous blood	A, B
2.	Capillary puncture	Published procedure	Capillary blood	A, B

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Explanatory notes:

- ¹ Established degrees of freedom according to MPA 00-09-..:
 - A Flexibility concerning the documented examination / sample collection procedure
 - B Flexibility concerning the technique
 - C Flexibility concerning the analytes / parameters
 - D Flexibility concerning the examined material
 - E Flexibility concerning the POCT delivery points

If no degree of freedom is specified, the laboratory cannot apply a flexible approach to the scope of accreditation for this examination.

Real-Time PCR Polymerase chain reaction in real time
HIT heparin-induced thrombocytopenia

[&]quot;This document is an appendix to the certificate of accreditation. In case of any discrepancies between the English and Czech versions, the Czech version shall prevail, both for the certificate appendix and the certificate itself."