



EA MLA Signatory
Český institut pro akreditaci, o.p.s.
Olšanská 54/3, 130 00 Praha 3

issues

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

CERTIFICATE OF ACCREDITATION

No. 211/2023

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

to 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 15189:2013

In its activities performed within the scope and for the period of validity of this Certificate, the Body is entitled to refer to this Certificate, provided that the accreditation is not suspended and the 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.: 657/2021 of 15. 12. 2021, or any administrative acts building upon it.

The Certificate of Accreditation is valid until: **6. 8. 2025**

Prague: 2. 5. 2023



Milena Lochmanová
Director of the Department of Medical Laboratories
Czech Accreditation Institute
Public Service Company

**The Appendix is an integral part of
Certificate of Accreditation No. 211/2023 of 02/05/2023**

Accredited entity according to ČSN EN ISO 15189:2013:

Ústřední vojenská nemocnice - Vojenská fakultní nemocnice Praha

CAB Number 8195, Clinical Laboratories

U Vojenské nemocnice 1200/1, 169 02 Praha 6

Examinations:

Ordinal number	Analyte/parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
222 - Transfusion Medicine					
1.	Blood types	Gel column agglutination (manual)	SOP/A-Sklad/001/v04, valid as of: 17/06/2021;	Plasma	-
2.	Blood types	Gel column agglutination (automatic)	SOP/A-Sklad/001/v04; valid as of: 17/06/2021; GALILEO NEO	Plasma	-
3.	Screening of anti-erythrocyte antibodies	Solid phase	SOP/A-Sklad/002/v03, valid as of: 09/04/2015; Galileo NEO	Plasma	-
4.	Screening of anti-erythrocyte antibodies	Gel column agglutination	SOP/A-Sklad/003/v04, valid as of: 27/08/2021	Plasma	-
5.	Examination of compatibility	Computer crossmatch	SOP/A-Sklad/004/v02, valid as of: 09/04/2015	Plasma	-
6.	Examination of compatibility	Gel column agglutination	SOP/A-Sklad/005/v03 Valid as of: 15/10/2018	Plasma	-
7.	Examination of compatibility	Solid phase	SOP/A-Sklad/006/v02, valid as of: 09/04/2015; Galileo NEO	Plasma	-
8.	Screening of anti-erythrocyte antibodies	Gel column agglutination	SOP/A-Sklad/007/v03, validity: 01/05/2016	Plasma	-
9.	Screening of anti-erythrocyte antibodies	Solid phase	SOP/A-Sklad/008/v02, valid as of: 09/04/2015; Galilo NEO	Plasma	-
10.	Direct antiglobulin test	Gel column agglutination	SOP/A-Sklad/009/v02, valid as of: 09/04/2015	Plasma	-



-7-

**The Appendix is an integral part of
Certificate of Accreditation No. 211/2023 of 02/05/2023**

Accredited entity according to ČSN EN ISO 15189:2013:

Ústřední vojenská nemocnice - Vojenská fakultní nemocnice Praha
CAB Number 8195, Clinical Laboratories
U Vojenské nemocnice 1200/1, 169 02 Praha 6

Ordinal number	Analyte/parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
801 – Clinical Biochemistry					
1.	Ions	Potentiometry	SOP/A-Bioch/012/v06, valid as of: 15/07/2022; SOP/A-Bioch/013/v06, valid as of: 15/07/2022; SOP/A-Bioch/014/v06, valid as of: 15/07/2022; cobas® pro	Serum	-
2.	Enzymes	Absorption spectrophotometry	SOP/A-Bioch/015/v05, valid as of: 15/07/2022; SOP/A-Bioch/016/v05, valid as of: 15/07/2022; SOP/A-Bioch/017/v05, valid as of: 15/07/2022; SOP/A-Bioch/036/v05, valid as of: 15/07/2022; SOP/A-Bioch/037/v05, valid as of: 15/07/2022; SOP/A-Bioch/038/v05, valid as of: 15/07/2022; cobas® pro	Serum	-
3.	Glucose	Absorption spectrophotometry	SOP/A-Bioch/018/v06 valid as of: 15/07/2022 cobas® pro	Serum, plasma	-
4.	Tumour markers	Immunoassay with luminometric detection	SOP/A-Bioch/023/v05, valid as of: 15/07/2022; SOP/A-Bioch/045/v04, valid as of: 15/07/2022; cobas® pro	Serum	-



**The Appendix is an integral part of
Certificate of Accreditation No. 211/2023 of 02/05/2023**

Accredited entity according to ČSN EN ISO 15189:2013:

Ústřední vojenská nemocnice - Vojenská fakultní nemocnice Praha
CAB Number 8195, Clinical Laboratories
U Vojenské nemocnice 1200/1, 169 02 Praha 6

Ordinal number	Analyte/parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
5.	Proteins	Absorption spectrophotometry	SOP/A-Bioch/029/v05, Valid as of: 15/07/2022; SOP/A-Bioch/033/v05. valid as of: 15/07/2022; cobas® pro	Serum	-
6.	Lipids	Absorption spectrophotometry	SOP/A-Bioch/031/v05, valid as of: 15/07/2022; SOP/A-Bioch/034/v05, valid as of: 15/07/2022; SOP/A-Bioch/035/v05, valid as of: 15/07/2022; SOP/A-Bioch/163/v01, valid as of: 15/07/2022; cobas® pro	Serum	-
7.	Non-protein nitrogenous substances	Absorption spectrophotometry	SOP/A-Bioch/032/v05, valid as of: 15/07/2022; SOP/A-Bioch/039/v05, valid as of: 15/07/2022; SOP/A-Bioch/052/v03, valid as of: 15/07/2022; cobas® pro	Serum	-
8.	Glycated haemoglobin	High-Performance Liquid Chromatography	SOP/A-Bioch/071/v02, valid as of: 25. 3. 2020; Tosoh G8	Blood	-
9.	Cardiac markers	Immunoassay with luminometric detection	SOP/A-Bioch/042/v04, valid as of: 15/07/2022; SOP/A-Bioch/043/v04, valid as of: 15/07/2022; cobas® pro	Serum	-



**The Appendix is an integral part of
Certificate of Accreditation No. 211/2023 of 02/05/2023**

Accredited entity according to ČSN EN ISO 15189:2013:

Ústřední vojenská nemocnice - Vojenská fakultní nemocnice Praha

CAB Number 8195, Clinical Laboratories

U Vojenské nemocnice 1200/1, 169 02 Praha 6

Ordinal number	Analyte/parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
10.	Total bilirubin	Absorption spectrophotometry	SOP/A-Bioch/049/v04, valid as of: 15/07/2022; cobas® pro	Serum	-
11.	Acid-base balance	Potentiometry; Amperometry	SOP/A-Bioch/053/v03, valid as of: 16. 4. 2020; ABL800 Flex	Blood	-
802 – Medical Microbiology					
1.	Bacteriological examination of clinical material	Microscopy; Aerobic culture; Anaerobic culture	SOP/A - OKM/01/v06, valid as of: 18/01/2023	Swab of wound, punctate, fistulae, abscess, redon, dialyzate, pus, tissue, decubitus, varicose ulster, acne, bile exudate, furuncle, gastric juice, middle ear, external auditory canal, ORL cavities, conjunctival sac, skin nidus	-
2.	Bacteriological examination of foreign bodies	Aerobic culture;	SOP/A - OKM/01/v06, valid as of: 18/01/2023	Drain, catheter, implant	-
3.	Bacteriological examination of urogenital tract	Microscopy; Microaerophilic culture	SOP/A - OKM/02/v05, valid as of: 05/10/2022	Vaginal, cervical, urethral swab, ejaculate, prostatic secretion	-
4.	Qualitative examination of susceptibility of bacteria	Disk diffusion test	SOP/A - OKM/03/v07, valid as of: 04/01/2023	Bacterial culture,	-
5.	Quantitative examination of susceptibility of bacteria	Diffusion gradient method	SOP/A - OKM/04/v06, valid as of: 06/04/2022;	Bacterial culture	-



**The Appendix is an integral part of
Certificate of Accreditation No. 211/2023 of 02/05/2023**

Accredited entity according to ČSN EN ISO 15189:2013:

Ústřední vojenská nemocnice - Vojenská fakultní nemocnice Praha

CAB Number 8195, Clinical Laboratories

U Vojenské nemocnice 1200/1, 169 02 Praha 6

Ordinal number	Analyte/parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
6.	Quantitative examination of susceptibility of bacteria	Automatic	SOP/A - OKM/04/v06, valid as of: 06/04/2022; VITEK 2	Bacterial culture	-
7.	Bacteriological examination of lower respiratory tract	Microscopy; Aerobic culture;	SOP/A - OKM/05/v03, valid as of: 17/03/2022	Sputum, BAL, ETK aspirate/swab	-
8.	Antigens of infectious agents of the respiratory tract	Immunochromatography	SOP/A - OKM/05/v03, valid as of: 17/03/2022	Urine	-
9.	Bacteriological examination of upper respiratory tract	Aerobic culture	SOP/A - OKM/06/v 04, valid as of: 17/03/2022	Cervical, nasal, oral cavity, nasopharyngeal, laryngeal swab	-
10.	Bacteriological examination of blood and primarily sterile body fluids	Aerobic culture; Anaerobic culture; (automatic)	SOP/A - OKM/07/v04, valid as of: 17/03/2022; BD Bactec FX	Blood, punctate, exudate, cerebrospinal fluid	-
11.	Identification of bacteria.	Phenotyping	SOP/A - OKM/08/v07, valid as of: 04/06/2022	Bacterial culture	-
12.	Identification of bacteria.	Mass spectrometry	SOP/A - OKM/08/v07, valid as of: 04/06/2022; IVD MALDI Biotyper system – Microflex LT/SH	Bacterial culture	-
13.	Bacteriological examination of cerebrospinal fluid	Microscopy; Aerobic culture	SOP/A - OKM/09/v06, valid as of: 06/04/2022	CSF	-
14.	Microbiological examination of urine, quantitative	Aerobic culture	SOP/A - OKM/10/v03, valid as of: 22/03/2022	Urine	-
15.	Microbiological examination of rectal swabs and stool	Aerobic culture; Anaerobic culture	SOP/A - OKM/11/v06, valid as of: 18/01/2023	Rectal swabs, stool	-
16.	Antigens of infectious agents	Immunochromatography	SOP/A - OKM/11/v06, valid as of: 18/01/2023	Rectal swabs, stool	-



**The Appendix is an integral part of
Certificate of Accreditation No. 211/2023 of 02/05/2023**

Accredited entity according to ČSN EN ISO 15189:2013:

Ústřední vojenská nemocnice - Vojenská fakultní nemocnice Praha

CAB Number 8195, Clinical Laboratories

U Vojenské nemocnice 1200/1, 169 02 Praha 6

Ordinal number	Analyte/parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
17.	Serotyping of intestinal pathogens	Agglutination	SOP/A - OKM/11/v06, valid as of: 18/01/2023	Bacterial culture	-
18.	Antibodies to infectious agents	Immunoassay with luminometric detection	SOP/A - OKM/20/v02, valid as of: 02/08/2022; SOP/A - OKM/17/v01, valid as of: 08/12/2022 SOP/A - OKM/18/v01, valid as of: 10/06/2022 LIAISON XL	Serum, plasma	-
19.	Antibodies to infectious agents	Immunoassay with photometric detection	SOP/A - OKM/19/v02, valid as of: 02/08/2022;	Serum, plasma	-
20.	Antibodies to infectious agents	Immunoblotting;	SOP/A - OKM/16/v02, valid as of: 07/04/2022	Serum, plasma, synovial fluid, joint punctate	-
21.	Hepatitis B virus surface antigen	Immunoassay with luminometric detection	SOP/A-Bioch/024/v06, valid as of: 15/07/2022; cobas® pro	Serum	-
22.	HIV virus markers	Immunoassay with luminometric detection	SOP/A-Bioch/025/v06, valid as of: 15/07/2022; cobas® pro	Serum	-
23.	Hepatitis C virus antibodies	Immunoassay with luminometric detection	SOP/A-Bioch/026/v05, valid as of: 15/07/2022; cobas® pro	Serum	-
24.	Detection of DNA of infectious agents	Real-Time PCR	SOP - OKM/26/v04, valid as of: 17/01/2023; SOP - OKM/32/v04, valid as of: 17/01/2023 RotorGene Q, CFX 96, CFX OPUS	Urine, ejaculate, swab from eye, endocervix, urethra, rectum and oropharynx	-
25.	Detection of DNA of infectious agents	Real-Time PCR	SOP - OKM/46/v03, valid as of: 17/01/2023; GeneXpert XVI	Blood	-



**The Appendix is an integral part of
Certificate of Accreditation No. 211/2023 of 02/05/2023**

Accredited entity according to ČSN EN ISO 15189:2013:

Ústřední vojenská nemocnice - Vojenská fakultní nemocnice Praha

CAB Number 8195, Clinical Laboratories

U Vojenské nemocnice 1200/1, 169 02 Praha 6

Ordinal number	Analyte/parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
26.	Detection of RNA of infectious agents	Real-Time PCR	SOP – OKM/50/v01, valid as of: 06/10/2022; SOP – OKM/36/v03, valid as of: 17/01/2023; GeneXpert XVI	Nasopharyngeal swab,	.
27.	Detection of RNA of infectious agents	Real-Time PCR	SOP – OKM/51/v01, valid as of: 11/01/2023; RotorGene Q, CFX 96,CFX OPUS	Nasopharyngeal swab, aspirate, BAL	.
813 - Allergology and Immunology Laboratory					
1.	C-reactive protein (CRP)	Immunoturbidimetry	SOP/A-Bioch/030/v05, valid as of: 15/07/2022; cobas® pro	Serum	-
815 - Nuclear Medicine Laboratory					
1.	Hormones	Immunoassay with luminometric detection	SOP/A-Bioch/019/v05, valid as of: 15/07/2022; SOP/A-Bioch/020/v06, valid as of: 15/07/2022; SOP/A-Bioch/021/v05, valid as of: 15/07/2022; SOP/A-Bioch/046/v04, valid as of: 15/07/2022; SOP/A-Bioch/047/v04, valid as of: 15/07/2022; cobas® pro	Serum	-
2.	Tumour markers	Immunoassay with luminometric detection	SOP/A-Bioch/022/v05, valid as of: 15/07/2022; SOP/A-Bioch/044/v04, valid as of: 15/07/2022; cobas® pro	Serum	-
3.	Myoglobin	Immunoassay with luminometric detection	SOP/A-Bioch/041/v05, valid as of: 15/07/2022; cobas® pro	Serum	-



**The Appendix is an integral part of
Certificate of Accreditation No. 211/2023 of 02/05/2023**

Accredited entity according to ČSN EN ISO 15189:2013:

Ústřední vojenská nemocnice - Vojenská fakultní nemocnice Praha

CAB Number 8195, Clinical Laboratories

U Vojenské nemocnice 1200/1, 169 02 Praha 6

Ordinal number	Analyte/parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
818 - Haematology Laboratory					
1.	Blood count with a with a five-part differential Leukocyte count	Fluorescent flow cytometry; Spectrophotometry-SLS method; Hydrodynamic focusing; Impedance method	SOPA-Hem/004/v09, valid as of: 14/10/2022; SOP/A-Hem/012/05, valid as of: 14/10/2022; Calibrator XN 103656; SYSMEX XN-10	Blood	-
2.	Activated partial thromboplastin time	Coagulation method with optical detection of coagulum	SOP/A-Hem/002/v06, valid as of: 20/09/2020; Cal 0020003700 IL; ACL TOP 550 and 500 IL	Plasma	-
3.	Prothrombin test	Coagulation method with optical detection of coagulum	SOP/A-Hem/003/v05, valid as of: 15/08/2020; Cal 0020003700 IL; ACL TOP 550 and 500 IL	Plasma	-
4.	Reticulocytes	Fluorescent flow cytometry	SOP/A-Hem/007/v05, valid as of: 14/10/2022; Sysmex XN 10 haematology analyzer	Blood	-
5.	Differential leukocyte count	Microscopy	SOP/A-Hem/013/v05, 14/10/2022	Blood	-
6.	Differential leukocyte count	Digital microscopy	SOP/A-Hem/013/v05, valid as of: 14/10/2022; Sysmex DI-60	Blood	-
7.	Fibrinogen	Coagulation method with optical detection of coagulum	SOP/A-Hem/001/v04, valid as of: 18/09/2017, Cal 0020003700 IL; ACL TOP 550 and 500 IL	Plasma	-
8.	Antithrombin	Chromogenic method	SOP/A-Hem/005/v06, valid as of: 15/11/2018; Cal 0020003700 IL; ACL TOP 550 and 500 IL	Plasma	-



-7-

**The Appendix is an integral part of
Certificate of Accreditation No. 211/2023 of 02/05/2023**

Accredited entity according to ČSN EN ISO 15189:2013:

Ústřední vojenská nemocnice - Vojenská fakultní nemocnice Praha

CAB Number 8195, Clinical Laboratories

U Vojenské nemocnice 1200/1, 169 02 Praha 6

Ordinal number	Analyte/parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
9.	Factor VIII	Coagulation method with optical detection of coagulum	SOP/A-Hem/008/v03, valid as of: 18/09/2017; Cal 0020003700 IL; ACL TOP 550 and 500 IL	Plasma	-
10.	D-dimers	Latex - Immunoturbidimetry	SOP/A-Hem/009/v03, 18/09/2017, Cal 0020007722 IL; ACL TOP 550 and 500 IL	Plasma	-
11.	Anti - Xa	Chromogenic method	SOP/A-Hem/006/v05, valid as of: 01/03/2019; Cal 0020300600 IL; ACL TOP 550 and 500 IL	Plasma	-

Specification of the scope of accreditation:

Field Nr. / Ordinal Number	Detailed information on activities within the scope of accreditation
222/1	Blood type AB0, Rh and Kell
801/1	Na ⁺ , K ⁺ , Cl ⁻
801/ 2	Alanine aminotransferase (ALT), Aspartate aminotransferase (AST), Gamma glutamyltransferase (GGT), Alkaline phosphatase (ALP), Alpha amylase (Total amylase), Pancreatic alpha amylase (Pancreatic amylase)
801/4	Free prostate specific antigen (FPSA), Carbohydrate tumor antigen (CA 125)
801/5	Total protein, albumin
801/6	Cholesterol, Triacylglycerols, HDL-cholesterol, LDL-cholesterol
801/7	Uric acid, Urea, Creatinine
801/9	Troponine T (hs TNT), N-terminal fragment proBNP (NT-proBNP)
801/11	pH, pO ₂ , pCO ₂
802/8	<i>Legionella pneumophila</i> , <i>Streptococcus pneumoniae</i>
802/14	Bacteria, yeasts
802/15	Bacteria, yeasts



**The Appendix is an integral part of
Certificate of Accreditation No. 211/2023 of 02/05/2023**

Accredited entity according to ČSN EN ISO 15189:2013:

Ústřední vojenská nemocnice - Vojenská fakultní nemocnice Praha

CAB Number 8195, Clinical Laboratories

U Vojenské nemocnice 1200/1, 169 02 Praha 6

Field Nr. / Ordinal Number	Detailed information on activities within the scope of accreditation
802/16	Adenoviruses, Noroviruses, Rotaviruses, <i>Helicobacter pylori</i> , GDH and <i>Clostridioides difficile</i> toxin
802/17	Serotyping of Salmonella, Shigella, Yersinia, Vibrio cholerae, E. coli
802/18	<i>Borrelia burgdorferi sensu lato</i> in IgM and IgG class (AB/BORR IgG CLIA, S_AB/BORR IgM CLIA, P_AB/BORR IgG CLIA, P_AB/BORR IgM CLIA) CMV (AB/CMV IgG CLIA, AB/BORR IgM CLIA) EBV(AB/VCA IgG CLIA, AB/VCA IgM CLIA, AB/EA IgG CLIA, AB/EBNA IgG CLIA)
802/19	<i>Clostridium Tetani</i> in IgG class (S_AB/TET IgG Elisa)
802/20	<i>Borrelia burgdorferi sensu lato</i> in IgM and IgG class (S_WB Borr IgG, S_WB Borr IgM, P_WB Borr IgG, P_WB Borr IgM, J_WB Borr IgG, J_WB Borr IgM)
802/21	Hepatitis B virus surface antigen (HBsAg)
802/22	Antibodies to HIV- 1/HIV-2 and HIV-1 p24 antigen (Anti HIV1/2+p24)
802/23	Hepatitis C virus antibodies (Anti-HCV) total
802/24	DNA <i>Chlamydia trachomatis</i> ; DNA <i>Neisseria gonorrhoeae</i>
802/25	DNA HBV
802/26	RNA SARS-CoV-2; RNA HCV
802/27	RNA SARS-CoV-2
815/1	Free triiodothyronine (FT3), Free thyroxine (FT4), Thyroid-stimulating hormone (TSH), Parathormone, Human chorionic gonadotropin (HCG)
815/2	Prostate specific antigen (PSA), Carcinoembryonic antigen (CEA)
818/1	WBC - Leukocytes, RBC - Erythrocytes, HGB - Haemoglobin, HCT - Haematocrit, PLT - Thrombocytes, MPV – Mean Plat.Vol., MCV - Mean.Corp.Vol., MCH - Mean Cor.Hgb., MCHC - Mean Cor.Hgb.Conc., RDW - Red Cell Distr.Width, PDW - PLT Distr. Width
818/2	APTT - patient time, APTT - control time, APTT - Ratio (R)
818/3	PT - patient time, PT - control time, PT - ratio, PT - INR
818/5	NK Neutrophils, NK Neutrophils absol, NK lymphocytes, NK Lymphocytes absol, NK monocytes, NK Monocytes absol, NK eosinophils, NK Eosinophils absol, NK basophils, NK Basophils absol]



The Appendix is an integral part of
Certificate of Accreditation No. 211/2023 of 02/05/2023

Accredited entity according to ČSN EN ISO 15189:2013:

Ústřední vojenská nemocnice - Vojenská fakultní nemocnice Praha
CAB Number 8195, Clinical Laboratories
U Vojenské nemocnice 1200/1, 169 02 Praha 6

Primary sample collection:

Ordinal Number ²	Sample collection technique	Identification of sample collection procedure	Collected material	Degrees of freedom ¹
1.	Venepuncture	SOP/COP/004/v03, valid as of: 20/12/2022	Venous blood	-
2.	Fingerstick	SOP/COP/004/v03, valid as of: 20/12/2022	Capillary blood	-

Explanatory notes:

¹ The laboratory does not apply a flexible approach to the scope of accreditation

Real-Time PCR Quantitative Real-Time Polymerase Chain Reaction

