



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. 391/2025

Zdravotní ústav se sídlem v Ostravě with registered office Partyzánské náměstí 2633/7, Moravská Ostrava, 702 00 Ostrava Company Registration No. 71009396

for the Medical Laboratory No. **8014**Centre of clinical laboratotarories

Scope of accreditation:

Laboratory diagnostics in the field of medical microbiology, cytogenetics and molecular genetics, allergology and clinical immunology, clinical biochemistry including shared examinations and collection of primary samples 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.: 505/2024 of 27/09/2024, and/or any administrative acts building upon it.

The Certificate of Accreditation is valid until: 25/04/2029

Prague: 25/07/2025





Signed in the Czech original: Milena Lochmanová on 25/07/2025

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:

Zdravotní ústav se sídlem v Ostravě

CAB Number 8014, Centre of Clinical Laboratories Partyzánské náměstí 2633/7, Moravská Ostrava, 702 00 Ostrava

Medical laboratory locations:

1. **Ostrava** Partyzánské náměstí 2633/7, Moravská Ostrava, 702 00 Ostrava

2. **Brno** Gorkého 56/6, 602 00 Brno

3. **Sample collection site Ostrava - Zábřeh** Poliklinika Zábřeh, s.r.o., Náměstí SNP č.1886/4, 700 30

Ostrava - Zábřeh

4. **Sample collection site Karviná** Poliklinika Karviná, Žižkova 2379/54a, 733 01 Karviná -

Mizerov

5. **Sample collection site VZP** Sokolská třída 1/267, Moravská Ostrava, 702 00 Ostrava

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://labprirucka.zuova.cz/sop/

1. Ostrava

Examinations:

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, plasma	A, B, C
2.	Enzymes	Absorption spectrophotometry	Commercial procedure	Serum, plasma	A, B, C
3.	Saccharides	Absorption spectrophotometry	Commercial procedure	Serum, plasma	A, B, C
4.	Lipids	Absorption spectrophotometry	Commercial procedure	Serum, plasma	A, B, C
5.	Non-protein nitrogenous compounds	Absorption spectrophotometry	Commercial procedure	Serum, plasma	A, B, C
6.	Glycated haemoglobin	High Performance Liquid Chromatography	Commercial procedure	Blood	A, B

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Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹				
	802 – Medical Microbiology								
1.	Virus detection	Cultivation on tissue culture	Published procedure	Clinical material	A, B, D				
2.	Virus detection	Virus isolation in suckling mice, intracerebral inoculation	Published procedure	Clinical material	A, B, D				
3.	Virus detection	Electron microscopy	Published procedure	Clinical material	A, B, D				
4.	HIV markers	Immunoassay with fluorescence detection	Commercial procedure	Body fluids	A, B, D				
5.	HIV markers	Immunoassay with luminometric detection	Commercial procedure	Body fluids	A, B, D				
6.	Antibodies to infectious agents	Virus neutralization test	Published procedure	Body fluids	A, B, C, D				
7.	Antigens of infectious agents	Immunoassay with photometric detection (manual)	Commercial procedure	Clinical material	A, B, C, D				
8.	Antigens of infectious agents	Immunoassay with photometric detection (automated)	Commercial procedure	Body fluids	A, B, C, D				
9.	Antibodies to infectious agents	Complement fixation reaction	Published procedure; Commercial procedure	Body fluids	A, B, C, D				
10.	Antibodies to infectious agents	Indirect immunofluorescence microscopy	Commercial procedure	Body fluids	A, B, C, D				
11.	Antibodies to infectious agents	Immunoassay with photometric detection (manual)	Published procedure; Commercial procedure	Body fluids	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
12.	Antibodies to infectious agents	Immunoassay with photometric detection (automated)	Commercial procedure	Body fluids	A, B, C, D
13.	Antibodies to infectious agents	Immunoblotting (manual)	Commercial procedure	Body fluids	A, B, C, D
14.	Antibodies to infectious agents	Immunoblotting (automated)	Commercial procedure	Body fluids	A, B, C, D
15.	Antibodies to infectious agents	Immunoassay with luminometric detection (automated)	Commercial procedure	Body fluids	A, B, C, D
16.	Antigens of infectious agents	Immunoassay with luminometric detection (automated)	Commercial procedure	Body fluids	A, B, C, D
17.	Antibodies to infectious agents	Agglutination (manual)	Commercial procedure	Body fluids	A, B, C, D
18.	Antibodies to infectious agents	Microscopic agglutination test	Published procedure	Body fluids	A, B, C, D
19.	Microbiological examination of rectal swab and stool	Aerobic culture; Anaerobic culture	Published procedure	Rectal swab, stool	A, B, C
20.	Microbiological examination of clinical material	Aerobic culture	Published procedure	Clinical material	A, B, C, D
21.	Microbiological examination of clinical material	Microscopy; Aerobic culture; Anaerobic culture	Published 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
22.	Microbiological examination of , primarily sterile body liquids	Microscopy; Aerobic culture; Anaerobic culture;	Published procedure	Liquid clinical material	A, B, C, D
23.	Microbiological examination of blood, primarily sterile body fluids and solid clinical samples	Aerobic culture; Anaerobic culture (automated)	Commercial procedure	Clinical material	A, B, C, D
24.	Quantitative microbiological examination of urine	Aerobic culture	Published procedure	Urine	A, B, C
25.	Microbiological examination of upper respiratory tract	Aerobic culture; Anaerobic culture	Published procedure	Material from the upper respiratory tract	A, B, C, D
26.	Microbiological examination of the lower respiratory tract	Microscopy; Aerobic culture; Anaerobic culture	Published procedure	Material from the lower respiratory tract	A, B, C, D
27.	Microbiological examination of urogenital tract	Microscopy; Aerobic culture; Anaerobic culture	Published procedure	Material from urogenital tract	A, B, C, D
28.	Reserved				
29.	Diagnostics of Neisseria gonorrhoeae	Aerobic culture	Published procedure	Clinical material	A, B, D
30.	Antigens of infectious agents	Agglutination	Commercial procedure	Body fluids	A, B, C, D
31.	Antigens of infectious agents	Immunochromatogra phy	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
32.	Toxins of infectious agents	Immunochromatogra phy	Commercial procedure	Bacterial culture, stool	A, B, C
33.	Identification of bacteria	Phenotyping	Published procedure; Commercial procedure	Bacterial culture	A, B
34.	Identification of bacteria	Agglutination	Commercial procedure; Published procedure	Bacterial culture	A, B, C
35.	Identification of microorganisms	Mass spectrometry	Commercial procedure	Bacterial culture, micromycete isolate, mycobacterial strain	A, B, C
36.	Detection and quantitative examination of sensitivity of urogenital mycoplasmas	Culture; Biochemical identification; Microdilution method	Commercial procedure	Clinical material	A, B, D
37.	Toxins of infectious agents	Immunoassay with fluorescence detection (automated)	Commercial procedure	Stool	A, B, C
38.	Toxins of infectious agents	Reverse passive latex agglutination	Commercial procedure	Microorganism culture, clinical material	A, B, C, D
39.	Qualitative examination of bacterial sensitivity	Disk diffusion method	Commercial procedure; Published procedure	Bacterial culture	A, B
40.	Quantitative examination of bacterial sensitivity	Microdilution method; E-test	Commercial procedure; Published procedure	Bacterial culture	A, B

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Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
41.	Clinically relevant antibiotic resistance screening	Aerobic culture; Immunochromatogra phy	Published procedure	Bacterial culture	A, B, D
42.	Clinically relevant antibiotic resistance screening	Mass spectrometry	Commercial procedure	Bacterial culture	A, B
43.	Microbiological examination of foreign materials	Aerobic culture	Published procedure	Foreign material	A, B, C, D
44.	Microbiological examination of foreign materials	Aerobic culture; Anaerobic culture	Published procedure	Foreign material	A, B, C, D
45.	Detection of mycobacteria	Fluorescence microscopy; Microscopy; Aerobic culture	Published procedure	Clinical material	A, B, D
46.	Reserved				
47.	Identification of mycobacteria	Microscopy; Aerobic culture; Phenotyping	Published procedure	Mycobacterial strain	A, B
48.	Reserved				
49.	Identification of mycobacteria	DNA strip technology (line probe assay)	Commercial procedure	Mycobacterial strain	A, B, C
50.	Quantitative examination of mycobacteria sensitivity	Microdilution method	Published procedure	Mycobacterial strain	A, B

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Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
51.	Qualitative examination of <i>Mycobacterium tuberculosis</i> complex	Metabolic method	Commercial procedure	Mycobacterial strain	A, B
52.	Examination of Pneumocystis jirovecii	Microscopy	Published procedure	Clinical material	A, B, D
53.	Mycological examination of clinical material	Microscopy; Culture	Published procedure	Clinical material	A, B, C, D
54.	Mycological examination of foreign materials	Culture	Published procedure	Foreign material	A, B, C, D
55.	Identification of micromycetes	Phenotyping	Published procedure	Yeasts and yeastlike microorganisms	A, B
56.	Identification of micromycetes	Agglutination	Published procedure	Yeasts and yeastlike microorganisms	A, B
57.	Identification of micromycetes	Microscopy; Culture	Published procedure	Filamentous fungus	A, B
58.	Qualitative examination of micromycetes sensitivity	Disk diffusion method	Published procedure; Commercial procedure	Micromycete isolate	A, B
59.	Quantitative examination of micromycetes sensitivity	Microdilution method; E-test	Published procedure; Commercial procedure	Micromycete isolate	A, B
60.	Parasitological examination	Microscopy	Published procedure	Stool, urine, sputum, biopsy, duodenal juice, punctate, worms or parts thereof	A, B

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Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹				
61.	Identification of intestinal protozoa	Microscopy	Published procedure	Stool	A, B				
62.	Examination of cryptosporidia and cyclospora	Microscopy	Published procedure	Stool	A, B				
63.	Examination for malaria	Microscopy	Published procedure	Capillary blood	A, B				
64.	Examination for enterobiosis	Microscopy	Published procedure	Perianal swab, imprint	A, B				
65.	Reserved								
66.	Diagnostics of Trichomonas vaginalis	Culture; Microscopy	Published procedure	Vaginal, cervical, and urethral secretions, vaginal microbial vaginal image	A, B				
67.	Detection of nucleic acids of infectious agents	Real-Time PCR	Commercial procedure	Clinical material	A, B, C, D				
68.	Detection of nucleic acids of infectious agents	Real-Time PCR (automated)	Commercial procedure	Clinical material	A, B, C, D				
69.	Detection of nucleic acids of infectious agents	Multiplex PCR (automated)	Commercial procedure	Clinical material	A, B, C, D				
70.	Detection of nucleic acids of infectious agents	DNA hybridization with signal amplification and luminometric detection	Commercial procedure	Cervical swab	A, B				
	813 - Allergology and Immunology Laboratory								

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Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
1.	Immunoglobulins	Immunonephelometr y (automated)	Commercial procedure	Body fluids	A, B, C, D
2.	Specific proteins	Immunonephelometr y (automated)	Commercial procedure	Body fluids	A, B, C, D
3.	Specific antibodies	Immunonephelometr y (automated)	Commercial procedure	Body fluids	A, B, C, D
4.	Specific IgE	Immunoassay with photometric detection (manual)	Commercial procedure	Serum, plasma	A, B, C
5.	Autoantibodies	Immunoassay with photometric detection (automated)	Commercial procedure	Serum, plasma	A, B, C
6.	Autoantibodies	Immunoassay with photometric detection (manual)	Commercial procedure	Serum, plasma	A, B, C
7.	Interferon gamma (IGRA)	Immunoassay with photometric detection (manual)	Commercial procedure	Blood	A, B, C
8.	Specific IgE	Immunoassay with s fluorimetric detection (automated)	Commercial procedure	Serum, plasma	A, B, C
9.	Immunoglobulin E	Immunoassay with s fluorimetric detection (automated)	Commercial procedure	Serum, plasma	A, B
10.	Typization of gammopathies	Electrophoresis followed by immunofixation (automated)	Commercial procedure	Body fluids	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			
11.	Autoantibodies	Immunoblotting (automated)	Commercial procedure	Body fluids	A, B, C, D			
12.	Autoantibodies	Immunoassay with luminometric detection (automated)	Commercial procedure	Body fluids	A, B, C, D			
13.	Autoantibodies	Indirect immunofluorescence (automated)	Commercial procedure	Serum, plasma	A, B, C			
14.	Autoantibodies	Indirect immunofluorescence (manual)	Commercial procedure	Serum, plasma	A, B, C			
15.	Immunophenotyping of cell populations	Flow cytometry (automated)	Commercial procedure	Blood	A, B, C			
	815 - Nuclear Medicine Laboratory							
1.	Hormones	Immunoassay with luminometric detection	Commercial procedure	Serum, plasma	A, B, C			

Primary sample collection:

Ordinal Number ²	Sample collection technique	Identification of sample collection procedure	Collected material	Degrees od freedom ¹
1.	Venipuncture	Published procedure	Venous blood	A, B
2.*	Capillary puncture	Published procedure	Capillary blood	A, B
3.	Swab	Published procedure	Swab from throat, nose, nasopharynx, larynx, external auditory canal, rectum	A, B
4.	Smear	Published procedure	Smear from tonsils, conjunctivae, skin, deposit (pus, punctate)	A, B

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Zdravotní ústav se sídlem v Ostravě

CAB Number 8014, Centre of Clinical Laboratories Partyzánské náměstí 2633/7, Moravská Ostrava, 702 00 Ostrava

2. Brno

Examinations:

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
		802 – Med	dical Microbiology		
1.	Microbiological examination of rectal swab	Aerobic culture; Anaerobic culture	Published procedure	Rectal swab, stool	A, B, C
2.	Microbiological examination of clinical material	Microscopy; Aerobic culture	Published procedure	Clinical material	A, B, C, D
3.	Microbiological examination of clinical material	Microscopy; Aerobic culture; Anaerobic culture	Published procedure	Clinical material	A, B, C, D
4.	Quantitative microbiological examination of urine	Aerobic culture	Published procedure	Urine	A, B, C
5.	Microbiological examination of upper respiratory tract	Aerobic culture	Published procedure	Material from the upper respiratory tract	A, B, C, D
6.	Microbiological examination of the lower respiratory tract	Microscopy Aerobic culture	Published procedure	Material from the upper respiratory tract	A, B, C, D
7.	Microbiological examination of urogenital tract	Microscopy; Aerobic culture Anaerobic culture	Published procedure	Material from the urogenital tract	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
8.	Microbiological examination of primary sterile body liquids	Microscopy; aerobic culture; anaerobic culture	Published procedure	Liquid clinical material	A, B, C
9.	Identification of bacteria	Phenotyping	Commercial procedure; Published procedure	Bacterial culture	A, B, C
10.	Identification of bacteria	Agglutination	Commercial procedure; Published procedure	Bacterial culture	A, B, C
11.	Identification of microorganisms	Mass spectrometry	Commercial procedure	Bacterial culture, micromycete isolate	A, B
12.	Detection and quantitative examination of sensitivity of urogenital mycoplasmas	Culture; Biochemical identification; Microdilution method	Commercial procedure	Clinical material	A, B, D
13.	Qualitative examination of bacterial sensitivity	Disk diffusion method	Commercial procedure; Published procedure	Bacterial culture	A, B
14.	Quantitative examination of bacterial sensitivity	E-test	Commercial procedure; Published procedure	Bacterial culture	A, B
		816 – Medica	al Genetics Laboratory		
1.	Examination of acquired chromosomal aberrations	Microscopy	Published procedure	Peripheral blood lymphocytes	A, B
2.	Examination of germline genome variants	Real-Time PCR	Commercial procedure;	Blood	A, B

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Primary sample collection:

Ordinal Number	Sample collection technique	Identification of sample collection procedure	Collected material	Degrees od freedom ¹
1.*	Venipuncture	Published procedure	Venous blood	A, B

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CAB Number 8014, Centre of Clinical Laboratories Partyzánské náměstí 2633/7, Moravská Ostrava, 702 00 Ostrava

3. Sample collection site Ostrava - Zábřeh

Primary sample collection:

Ordinal Number	Sample collection technique	Identification of sample collection procedure	Collected material	Degrees od freedom ¹
1.	Venipuncture	Published procedure	Venous blood	A, B
2.*	Capillary puncture	Published procedure	Capillary blood	A, B
3.	Swab	Published procedure	Swab from throat, nose, nasopharynx, larynx, external auditory canal, rectum	A, B
4.	Smear	Published procedure	Smear from tonsils, conjunctivae, skin, deposit	A, B

4. Sample collection site Karviná

Primary sample collection:

Ordinal Number	Sample collection technique	Identification of sample collection procedure	Collected material	Degrees od freedom ¹
1.	Venipuncture	Published procedure	Venous blood	A, B
2.*	Capillary puncture	Published procedure	Capillary blood	A, B
3.	Swab	Published procedure	Swab from throat, nose, nasopharynx, larynx, external auditory canal, rectum	A, B
4.	Smear	Published procedure	Smear from tonsils, conjunctivae, skin, deposit	A, B

5. Sample collection site VZP

Primary sample collection:

Ordinal Number	Sample collection technique	Identification of sample collection procedure	Collected material	Degrees od freedom ¹
1.	Venipuncture	Published procedure	Venous blood	A, B
2.*	Capillary puncture	Published procedure	Capillary blood	A, B
3.	Swab	Published procedure	Swab from throat, nose, nasopharynx, larynx, external auditory canal, rectum	A, B
4.	Smear	Published procedure	Smear from tonsils, conjunctivae, skin, deposit	A, B

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CAB Number 8014, Centre of Clinical Laboratories Partyzánské náměstí 2633/7, Moravská Ostrava, 702 00 Ostrava

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.

² If the Laboratory is able to carry out sample collections outside its permanent locations, these collections are marked with an asterisk next to the Ordinal Number

IGRA interferon gama release assay

Micromycetes yeasts, yeast-like microorganisms, filamentous fungi

Real-Time PCR Polymerase Chain Reaction in real time

[&]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."