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. **185/2024**

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 Laboratories

Scope of accreditation:

Laboratory diagnostics in the field of medical microbiology, cytogenetics, allergology and clinical immunology, 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 Conformity Assessment 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.: 135/2023 of 27. 3. 2023, or any administrative acts building upon it.

The Certificate of Accreditation is valid until: **25. 4. 2029**

Prague: 25. 4. 2024

Český institut pro akreditaci, o.p.s.
-1-

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

The Appendix is an integral part of
Certificate of Accreditation No. 185/2024 of 25/04/2024

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

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 method procedure/ equipment	Examined material	Degrees of freedom[1]
802 - Medical microbiology					
1.	Direct virus detection	Cultivation on tissue cultures	Published procedure	Clinical material	A, B, D
2.	Direct virus detection	Virus isolation in suckling mice, intracerebral inoculation	Published procedure	Clinical material	A, B, D
3.	Direct virus detection	Electron microscopy	Published procedure	Clinical material	A, B, D
4.	HIV markers	Immunoassay with luminometric detection	Commercial procedure	Serum, plasma	A, B
5.	Antibodies to infectious agents	Virus neutralization test	Published procedure	Serum, plasma, cerebrospinal fluid	A, B, C
6.	Antigens of infectious agents	Immunoassay with photometric detection (manual)	Commercial procedure	Clinical material	A, B, C, D
7.	Antigens of infectious agents	Immunoassay with photometric detection (automatic)	Commercial procedure	Body fluids	A, B, C, D
8.	Antibodies to infectious agents	Complement fixation reaction	Published procedure; Commercial procedure	Body fluids	A, B, C, D
9.	Antibodies to infectious agents	Indirect immunofluorescence microscopy	Commercial procedure	Body fluids	A, B, C, D

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Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of method procedure/ equipment	Examined material	Degrees of freedom[1]
10.	Antibodies to infectious agents	Immunoassay with photometric detection (manual)	Published procedure; Commercial procedure	Body fluids	A, B, C, D
11.	Antibodies to infectious agents	Immunoassay with photometric detection (automatic)	Commercial procedure	Body fluids	A, B, C, D
12.	Antibodies to infectious agents	Immunoblotting (manual)	Commercial procedure	Body fluids	A, B, C, D
13.	Antibodies to infectious agents	Immunoblotting (automatic)	Commercial procedure	Body fluids	A, B, C, D
14.	Antibodies to infectious agents	Immunoblotting (manual)	Commercial procedure	Body fluids	A, B, C, D
15.	Antibodies to infectious agents	Immunoassay with luminometric detection (automatic)	Commercial procedure	Body fluids	A, B, C, D
16.	Direct antigens detection	Immunoassay with luminometric detection (automatic)	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 method procedure/ equipment	Examined material	Degrees of freedom[1]
22.	Microbiological examination of cerebrospinal fluid	Microscopy; Aerobic culture; Anaerobic culture;	Published procedure	Cerebrospinal fluid	A, B, C
23.	Microbiological examination of blood, primarily sterile body fluids and solid clinical samples	Aerobic culture; Anaerobic culture (automatic)	Commercial procedure	Clinical material	A, B, C, D
24.	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	Aerobic culture; Anaerobic culture	Published procedure	Material from urogenital tract	A, B, C, D
28.	Microbiological examination of urogenital tract	Microscopy	Published procedure	Microbial Vaginal Image (MOP)	A, B, C
29.	Diagnostics of *Neisseria gonorrhoeae*	Aerobic culture	Published procedure	Clinical material	A, B, D
30.	Detection of bacterial antigens	Agglutination	Commercial procedure	Body fluid	A, B, C, D
31.	Detection of bacterial antigens	Immunochromatography	Commercial procedure	Clinical material	A, B, C, D
32.	Detection of bacterial toxins	Immunochromatography	Commercial procedure	Bacterial culture, stool	A, B, C

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Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of method procedure/ equipment	Examined material	Degrees of freedom[1]
33.	Identification of bacteria	Phenotyping	Published procedure; Commercial procedure	Bacterial culture	A, B, C
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 of urogenital mycoplasmas	Phenotyping	Commercial procedure	Clinical material	A, B, C, D
37.	Detection of bacterial toxins	Immunoassay with photometric detection detekcí (automatic)	Commercial procedure	Stool	A, B, C
38.	Detection of bacterial toxins	Reverse passive latex agglutination	Commercial procedure	Bacterial culture, stool	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
41.	Detection of beta-lactamase production	Phenotyping	Published procedure	Bacterial culture	A, B
42.	Detection of beta-lactamase production	Mass spectrometry	Commercial procedure	Bacterial culture	A, B
43.	Microbiological examination of foreign materials	Aerobic culture	Published procedure	Foreign material	A, B, C, D

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Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of method procedure/ equipment	Examined material	Degrees of freedom[1]
44.	Microbiological examination of foreign materials	Aerobic culture; Anaerobic culture	Published procedure	Foreign material	A, B, C, D
45.	Detection of mycobacteria	Fluorescence microscopy; Aerobic culture	Published procedure	Clinical material	A, B, D
46.	Detection of mycobacteria	Microscopy	Published procedure	Clinical material	A, B, D
47.	Identification of mycobacteria	Microscopy; Aerobic culture	Published procedure	Mycobacterial strain	A, B
48.	Identification of mycobacteria	Phenotyping	Published procedure	Mycobacterial strain	A, B
49.	Identification of mycobacteria	PCR with reverse hybridisation	Commercial procedure	Mycobacterial strain	A, B, C
50.	Quantitative examination of mycobacteria sensitivity	Microdilution method	Published procedure	Mycobacterial strain	A, B
51.	Qualitative examination of mycobacteria sensitivity	Metabolic method	Commercial procedure	Mycobacterial strain	A, B
52.	Detection 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

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Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of method procedure/ equipment	Examined material	Degrees of freedom[1]
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
61.	Identification of intestinal protozoa	Microscopy	Published procedure	Stool	A, B
62.	Identification 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.	Diagnostics of *Trichomonas vaginalis*	Microscopy	Published procedure	Vaginal, cervical and urethral secretions, Microbial Vaginal Image (MOP)	A, B
66.	Diagnostics of *Trichomonas vaginalis*	Culture; Microscopy	Published procedure	Clinical material	A, B

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Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of method procedure/ equipment	Examined material	Degrees of freedom[1]
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 (automatic)	Commercial procedure	Clinical material	A, B, C, D
69.	Detection of nucleic acids of infectious agents	Multiplex PCR (automatic)	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					
1.	Immunoglobulins	Immunonephelometry (automatic)	Commercial procedure	Body fluids	A, B, C, D
2.	Specific proteins	Immunonephelometry (automatic)	Commercial procedure	Body fluids	A, B, C, D
3.	Specific antibodies	Immunonephelometry (automatic)	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 (automatic)	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

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Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of method procedure/ equipment	Examined material	Degrees of freedom[1]
8.	Specific IgE	Immunoassay with s fluorimetric detection (automatic)	Commercial procedure	Serum, plasma	A, B, C
9.	Immunoglobulin E	Immunoassay with s fluorimetric detection (automatic)	Commercial procedure	Serum, plasma	A, B
10.	Typization of gammopathies	Electrophoresis followed by immunofixation (automatic)	Commercial procedure	Body fluids	A, B, D
11.	Autoantibodies	Immunoblotting (automatic)	Commercial procedure	Body fluids	A, B, C, D
12.	Autoantibodies	Immunoassay with luminometric detection (automatic)	Commercial procedure	Body fluids	A, B, C, D
13.	Autoantibodies	Indirect immunofluorescence (automatic)	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 (automatic)	Commercial procedure	Blood	A, B, C
816 - Medical Genetics Laboratory					
1.	Examination of HLA system	PCR - SSO	Commercial procedure	Blood	A, B, C, D

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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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2. **Brno**

Examinations:

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of method procedure/ equipment	Examined material	Degrees of freedom[1]
802 - Medical 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.	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	Aerobic culture Anaerobic culture	Published procedure	Material from the urogenital tract	A, B, C, D
8.	Microbiological examination of urogenital tract	Microscopy	Published procedure	Microbial Vaginal Image (MOP)	A, B, C
9.	Identification of microorganisms	Phenotyping	Commercial procedure; Published procedure	Bacterial culture	A, B, C

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Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of method procedure/ equipment	Examined material	Degrees of freedom[1]
10.	Identification of microorganisms	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 of urogenital mycoplasma	Phenotyping	Commercial procedure	Clinical material	A, B, C, 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
15.	Detection of beta-lactamase production	Phenotyping	Published procedure	Bacterial culture	A, B
816 - Medical Genetics Laboratory					
1.	Examination of acquired chromosomal aberrations	Microscopy	Published procedure	Peripheral blood lymphocytes	A, B

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

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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

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
PCR – SSO	Polymerase Chain Reaction with Sequence Specific Oligosondes
Real-Time PCR	Polymerase Chain Reaction in real time