



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. 373/2025

Laboratoře Mikrochem a.s. with registered office Nezvalova 984/2, Hodolany, 779 00 Olomouc Company Registration No. 60777907

for the Medical Laboratory No. **8062**Mikrochem Laboratories

Scope of accreditation:

Laboratory diagnostics in the field of medical microbiology, allergology and clinical immunology and primary sampling 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.: 259/2024 of 04/06/2024, and/or any administrative acts building upon it.

The Certificate of Accreditation is valid until: 20/10/2026

Prague: 21/07/2025





Signed in the Czech original: Milena Lochmanová on 21/07/2025

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:

Laboratoře Mikrochem a.s.

CAB Number 8062, Mikrochem Laboratories Nezvalova 984/2, Hodolany, 779 00 Olomouc

Medical laboratory locations:

Workplace Olomouc
 Workplace Přerov
 Čechova 988/8, 750 02 Přerov

3. **Workplace Šumperk** Nerudova 1195/34, 787 01 Šumperk

Workplace Valašské Meziříčí Vsetínská 854/60a,757 01 Valašské Meziříčí
 Sample Collection Room Šumperk Dr. E. Beneše 2871/5, 787 01 Šumperk

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
www.michem.cz/rizeni-kvality.

1. Workplace Olomouc

Examinations:

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
		802 – Medical 1	Microbiology		
1.	Quantitative microbiological examination of urine	Aerobic culture (automated)	Commercial procedure	Urine	A, B
2.	Quantitative microbiological examination of urine	Aerobic culture (manual); Microscopy;	Published procedure	Urine	A, B
3.	Bacteriological examination of rectal swab	Aerobic culture	Published procedure	Rectal swab	A, B
4.	Microbiological examination of upper respiratory tract	Aerobic culture	Published procedure	Material from upper respiratory tract	A, B, D
5.	Microbiological examination of lower respiratory tract	Microscopy; Aerobic culture	Published procedure	Material from lower 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
6.	Microbiological examination of urogenital tract	Aerobic culture	Published procedure	Material from urogenital tract	A, B, D
7.	Microbiological examination of clinical material	Aerobic culture	Published procedure	Clinical material	A, B, D
8.	Microbiological examination of primarily sterile body fluids	Aerobic culture; Anaerobic culture; Microscopy	Published procedure	Liquid clinical material	A, B, D
9.	Microbiological examination of clinical material	Aerobic culture; Anaerobic culture	Published procedure	Clinical material	A, B, D
10.	Microbiological examination of clinical material	Aerobic culture; Anaerobic culture; Microscopy	Published procedure	Pus	A, B
11.	Microbiological examination of foreign bodies	Aerobic culture; Anaerobic culture	Published procedure	Foreign bodies	A, B, D
12.	Antibiotic susceptibility testing	Diffusion disk test	Published procedure	Bacterial culture	A, B
13.	Identification of the microorganisms	Phenotyping	Published procedure	Microorganism culture	A, B
14.	Identification of bacteria	Agglutination	Published procedure	Bacterial culture	A, B
15.	Antibodies against infectious agents	Immunoassay with photometric detection (automated)	Commercial procedure	Serum	A, B, C
16.	Antibodies against infectious agents	Immunoassay with photometric detection (manual)	Commercial procedure	Serum	A, B, C
17.	Antibodies against infectious agents	Imunoblotting (manual)	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
18.	Antigens of infectious agents	Immunoassay with photometric detection (manual)	Commercial procedure	Serum	A, B, C
19.	Antibodies against infectious agents	Immunoassay with luminometric detection	Commercial procedure	Serum, plasma	A, B, C
20.	Antigens of infectious agents	Immunoassay with luminometric detection	Commercial procedure	Serum, plasma	A, B, C
21.	Detection of nucleic acids of infectious agents	Real-Time PCR (manual)	Commercial procedure	Clinical material	A, B, C, D
22.	Antibodies against infectious agents	Immunoassay with luminometric detection	Commercial procedure	Serum	A, B, C
23.	Stool Ova and Parasite Test	Microscopy	Published procedure	Stool	A
24.	Enterobiasis examination	Microscopy	Published procedure	Perianal imprint	A
25.	HIV markers	Immunoassay with luminometric detection	Commercial procedure	Serum, plasma	A, B, C
26.	Identification of the microorganism	Mass spectrometry (automated)	Commercial procedure	Microorganism culture	A, B, D
		813 - Allergology and In	ımunology Laboratory		
1.	Antinuclear autoantibodies (ANA)	Indirect immunofluorescence (manual)	Commercial procedure	Serum	A, B
2.	Immunoglobulins	Immunonephelometry (automated)	Commercial procedure	Serum	A, B

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Ordina Numbe	•	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
3.	Antibodies against tissue transglutaminase	Immunoassay with photometric detection (manual)	Commercial procedure	Serum	A, B

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CAB Number 8062, Mikrochem Laboratories Nezvalova 984/2, Hodolany, 779 00 Olomouc

Primary sample collection:

Ordinal Number	Sample collection technique	Identification of sample collection procedure	Collected material	Degrees of freedom ¹
1.	Swab	Published procedure	Swab from throat, tonsils, nasopharynx, nose, rectum	A, B
2.	Smear	Published procedure	Perianal imprint	A
3.	Venepuncture	Published procedure	Venous blood	A, B

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2. Workplace Přerov

Examinations:

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
		802 – Medical	l Microbiology		
1.	Quantitative microbiological examination of urine	Aerobic culture	Published procedure	Urine	A, B
2.	Microbiological examination of rectal swab	Aerobic culture	Published procedure	Rectal swab	A, B
3.	Microbiological examination of upper respiratory tract	Aerobic culture	Published procedure	Material from upper respiratory tract	A, B, D
4.	Microbiological examination of lower respiratory tract	Microscopy; Aerobic culture	Published procedure	Material from lower respiratory tract	A, B, D
5.	Microbiological examination of urogenital tract	Aerobic culture	Published procedure	Material from urogenital tract	A, B, D
6.	Microbiological examination of clinical material	Aerobic culture	Published procedure	Clinical material	A, B, D
7.	Microbiological examination of primarily sterile body fluids	Microscopy; Aerobic culture; Anaerobic culture	Published procedure	Liquid clinical material	A, B, D
8.	Microbiological examination of clinical material	Aerobic culture; Anaerobic culture	Published procedure	Clinical material	A, B, D
9.	Microbiological examination of clinical material	Microscopy; Aerobic culture; Anaerobic culture	Published procedure	Pus	A, B
10.	Microbiological examination of	Aerobic culture; Anaerobic culture	Published procedure	Foreign bodies	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
	foreign bodies				
11.	Antibiotic susceptibility testing	Diffusion disk test	Published procedure	Bacterial culture	A, B
12.	Identification of the microorganisms	Phenotyping	Published procedure	Microorganisms culture	A, B
13.	Identification of bacteria	Agglutination	Published procedure	Bacterial culture	A, B

Primary sample collection:

Ordinal Number	Sample collection technique	Identification of sample collection procedure	Collected material	Degrees of freedom ¹
1.	Swab	Published procedure	Swab from throat, tonsils, nasopharynx, nose, rectum	A, B
2.	Smear	Published procedure	Perianal imprint	A
3.	Venepuncture	Published procedure	Venous blood	A, B

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3. Workplace Šumperk

Examinations:

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹				
	802 – Medical Microbiology								
1.	Quantitative microbiological examination of urine	Aerobic culture	Published procedure	Urine	A, B				
2.	Microbiological examination of rectal swab	Aerobic culture	Published procedure	Rectal swab	A, B				
3.	Microbiological examination of upper respiratory tract	Aerobic culture	Published procedure	Material from upper respiratory tract	A, B, D				
4.	Microbiological examination of lower respiratory tract	Microscopy; Aerobic culture	Published procedure	Material from lower respiratory tract	A, B, D				
5.	Microbiological examination of urogenital tract	Aerobic culture	Published procedure	Material from urogenital tract	A, B, D				
6.	Microbiological examination of clinical material	Aerobic culture	Published procedure	Clinical material	A, B, D				
7.	Microbiological examination of primarily sterile body fluids	Microscopy; Aerobic culture; Anaerobic culture	Published procedure	Liquid clinical material	A, B, D				
8.	Microbiological examination of clinical material	Microscopy; Aerobic culture; Anaerobic culture	Published procedure	Pus	A, B				
9.	Microbiological examination of foreign bodies	Aerobic culture; Anaerobic culture	Published procedure	Foreign bodies	A, B, D				
10.	Microbiological examination of clinical	Aerobic culture;	Published procedure	Clinical material	A, B, D				

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Laboratoře Mikrochem a.s.

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
	material	Anaerobic culture			
12.	Antibiotic susceptibility testing	Diffusion disk test	Published procedure	Bacterial culture	A, B
12.	Identification of the microorganisms	Phenotyping	Published procedure	Microorganism culture	A, B
13.	Identification of bacteria	Agglutination	Published procedure	Bacterial culture	A, B
14.	Detection of mycobacteria	Microscopy; Aerobic culture	Published procedure	Clinical material	A, B, D
15.	Identification of mycobacteria	Immunochromatograp hy	Commercial procedure	Mycobacterial strain	A, B
16.	Antibodies against infectious agents	Immunoblotting	Commercial procedure	Serum	A, B
17.	Stool Ova and Parasite Test	Microscopy	Published procedure	Stool	A
18.	Enterobiasis examination	Microscopy	Published procedure	Perianal imprint	A

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4. Workplace Valašské Meziříčí

Primary sample collection:

Ordinal Number	Sample collection technique	Identification of sample collection procedure	Collected material	Degrees of freedom ¹
1.	Swab	Published procedure	Swab from throat, tonsils, nasopharynx, nose, rectum	A, B
2.	Smear	Published procedure	Perianal imprint	A
3.	Venepuncture	Published procedure	Venous blood	A, B

5. Sample Collection Room Šumperk

Primary sample collection:

Ordinal Number	Sample collection technique	Identification of sample collection procedure	Collected material	Degrees of freedom ¹
1.	Swab	Published procedure	Swab from throat, tonsils, nasopharynx, nose, rectum	A, B
2.	Smear	Published procedure	Perianal imprint	A
3.	Venepuncture	Published procedure	Venous blood	A, B

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

[&]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."