



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. 703/2025

Fakultní nemocnice u sv. Anny v Brně
with registered office Pekařská 664/53, 602 00 Brno
Company Registration No. 00159816

for the Medical Laboratory No. **8261**
Laboratories of the Institute of Microbiology

Scope of accreditation:

Examination in the field of medical microbiology 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.: 637/2024 of 29/11/2024, and/or any administrative acts building upon it.

The Certificate of Accreditation is valid until: **30/12/2030**

Prague: 30/12/2025



Signed in the Czech original:
Milena Lochmanová on 30/12/2025

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

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

**The Appendix is an integral part of
Certificate of Accreditation No. 703/2025 of 30/12/2025**

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

Fakultní nemocnice u sv. Anny v Brně
CAB number 8261, Laboratories of the Institute of Microbiology
Pekařská 664/53, 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:

www.fnusa.cz/pro-pacienty-a-navstevy/zdravotnicka-pracoviste/mikrobiologicky-ustav/.

Examinations:

Ordinal number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
802 – Medical Microbiology					
1.	Antibodies against infectious agents	Immunoassay with photometric detection	Commercial procedure	Body fluids	A, B, C, D
2.	Antigens of infectious agents	Immunoassay with luminometric detection	Commercial procedure	Body fluids	A, B, C, D
3.	Antigens of infectious agents	Immunoassay with photometric detection	Commercial procedure	Body fluids	A, B, C, D
4.	Antibodies against infectious agents	Immunoassay with luminometric detection	Commercial procedure	Body fluids	A, B, C, D
5.	Antibodies against infectious agents	Immunoblotting	Commercial procedure	Body fluids	A, B, C, D
6.	HIV markers	Immunoassay with luminometric detection	Commercial procedure	Body fluids	A, B, C, D
7.	Non-specific antibodies against <i>Treponema pallidum</i>	Agglutination	Commercial procedure	Body fluids	A, B, D
8.	Detection of nucleic acids of infectious agents	Real-Time PCR	Commercial procedure	Clinical material	A, B, C, D
9.	Microbiological examination of blood and primarily sterile body fluids	Aerobic culture; Anaerobic culture; (automated)	Commercial procedure	Liquid clinical material	A, B, D

**The Appendix is an integral part of
Certificate of Accreditation No. 703/2025 of 30/12/2025**

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

Fakultní nemocnice u sv. Anny v Brně
CAB number 8261, Laboratories of the Institute of Microbiology
Pekařská 664/53, 602 00 Brno

Ordinal number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom¹
10.	Microbiological examination of primarily sterile body fluids	Microscopy; Aerobic culture; Anaerobic culture	Commercial procedure	Liquid clinical material	A, B, C, D
11.	Microbiological examination of clinical material	Aerobic culture	Commercial procedure	Clinical material	A, B, C, D
12.	Clinically relevant antibiotic resistance screening	Aerobic culture	Commercial procedure	Clinical material	A, B, C, D
13.	Microbiological examination of clinical material	Microscopy; Aerobic culture; Anaerobic culture	Commercial procedure	Clinical material	A, B, C, D
14.	Microbiological examination of foreign bodies	Aerobic culture	Commercial procedure	Foreign bodies	A, B, C, D
15.	Microbiological examination of upper respiratory tract	Aerobic culture	Commercial procedure	Material of upper respiratory tract	A, B, C, D
16.	Microbiological examination of the lower respiratory tract	Microscopy; Aerobic culture	Commercial procedure	Material of lower respiratory tract	A, B, C, D
17.	Quantitative microbiological examination of urine	Aerobic culture	Commercial procedure	Urine	A, B
18.	Microbiological examination of urogenital tract	Microscopy; Aerobic culture; Anaerobic culture	Commercial procedure	Genitourinary system material	A, B, C, D
19.	Microbiological examination of rectal swab	Aerobic culture	Commercial procedure	Rectal swab, stool	A, B

**The Appendix is an integral part of
Certificate of Accreditation No. 703/2025 of 30/12/2025**

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

Fakultní nemocnice u sv. Anny v Brně
CAB number 8261, Laboratories of the Institute of Microbiology
Pekařská 664/53, 602 00 Brno

Ordinal number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
20.	Mycological examination of skin lesions	Microscopy; Culture	Commercial procedure	Clinical material	A, B, C, D
21.	Mycological examination of clinical material	Microscopy; Culture	Commercial procedure	Clinical material	A, B, C, D
22.	Identification of the microorganism	Mass spectrometry	Commercial procedure	Bacterial culture, yeast culture, filamentous fungi	A, B, C
23.	Identification of bacteria	Agglutination	Commercial procedure	Bacterial culture	A, B
24.	Identification of the microorganism	Biochemical identification	Commercial procedure	Bacterial culture	A, B, C
25.	Qualitative examination of microorganism sensitivity	Disk diffusion test	Commercial procedure	Bacterial culture	A, B, C
26.	Quantitative examination of microorganism sensitivity	Microdilution method; E-test	Commercial procedure	Bacterial culture, yeast culture, filamentous fungi	A, B, C
27.	Parasitological examination of stool	Microscopy	Commercial procedure	Stool	A, B
28.	Identification of intestinal protozoa	Microscopy	Commercial procedure	Stool	A, B
29.	Enterobiosis examination	Microscopy	Commercial procedure	Perianal swab, imprint	A, B
30.	Diagnostics of <i>Trichomonas vaginalis</i>	Microscopy	Commercial procedure	Vaginal, cervical, urethral secretions	A, B

**The Appendix is an integral part of
Certificate of Accreditation No. 703/2025 of 30/12/2025**

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

Fakultní nemocnice u sv. Anny v Brně
CAB number 8261, Laboratories of the Institute of Microbiology
Pekařská 664/53, 602 00 Brno

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

"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. "