



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. 57/2026

Fakultní nemocnice Brno
with registered office Jihlavská 340/20, Bohunice, 625 00 Brno
Company Registration No. 65269705

for the Medical Laboratory No. 8060
Institute of Laboratory Medicine

Scope of accreditation:

Laboratory diagnostics in the field of clinical biochemistry, allergology and clinical immunology, medical microbiology including shared examinations 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.: 40/2025 of 27/01/2025, and/or any administrative acts building upon it.

The Certificate of Accreditation is valid until: **03/02/2031**

Prague: 03/02/2026



Signed in the Czech original:
Milena Lochmanová on 03/02/2026

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. 57/2026 of 03/02/2026**

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

Fakultní nemocnice Brno
CAB Number 8060, Institute of Laboratory Medicine
Jihlavská 340/20, Bohunice, 625 00 Brno

Medical laboratory locations:

1. **Clinical Biochemistry Department (OKB), NBP Workplace**
Jihlavská 340/20, 625 00 Brno
2. **Clinical Biochemistry Department (OKB), NBP Workplace, Obilní trh**
Obilní trh 526/11, 625 00 Brno
3. **Clinical Microbiology and Immunology Department (OKMI)**
Jihlavská 340/20, 625 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://www.fnbrno.cz/areal-bohunice/ustav-laboratorni-mediciny/management-kvality/t7857>*

1. **Clinical Biochemistry Department (OKB), NBP Workplace**

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, urine	A, B, C
2.	Minerals	Absorption spectrophotometry	Commercial procedure	Serum, plasma, urine	A, B, C
3.	Enzymes	Absorption spectrophotometry	Commercial procedure	Serum, plasma	A, B, C
4.	Glucose	Absorption spectrophotometry	Commercial procedure	Serum, plasma, cerebrospinal fluid	A, B
5.	Lipids	Absorption spectrophotometry	Commercial procedure	Serum, plasma	A, B, C
6.	Non-protein nitrogenous compounds	Absorption spectrophotometry	Commercial procedure	Serum, plasma, urine	A, B, C
7.	Proteins	Absorption spectrophotometry	Commercial procedure	Body fluids	A, B, C, D
8.	Pigments	Absorption spectrophotometry	Commercial procedure	Serum, plasma	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
9.	Lactate	Absorption spectrophotometry	Commercial procedure	Plasma, cerebrospinal fluid	A, B
10.	Tumour markers	Immunoassay with luminometric detection	Commercial procedure	Serum, plasma	A, B, C
11.	Hormones	Immunoassay with luminometric detection	Commercial procedure	Serum, plasma	A, B, C
12.	Hormones	Immunoassay with luminometric detection	Commercial procedure	Serum, plasma	A, B, C
13.	Proteins	Immunonephelometry	Commercial procedure	Cerebrospinal fluid, urine	A, B, C
813 - Allergology and Immunology Laboratory					
1.	C-reactive protein (CRP)	Immunoturbidimetry	Commercial procedure	Serum, plasma	A, B
2.	Immunoglobulins	Immunoturbidimetry	Commercial procedure	Serum, plasma	A, B, C
3.	Immunoglobulins	Immunonephelometry	Commercial procedure	Cerebrospinal fluid	A, B, C
4.	Specific proteins	Immunonephelometry	Commercial procedure	Serum, plasma	A, B, C
815 - Nuclear Medicine Laboratory					
1.	Tumour markers	Immunoassay with luminometric detection	Commercial procedure	Serum, plasma	A, B, C
2.	Hormones	Immunoassay with luminometric detection	Commercial procedure	Serum, plasma	A, B, C
3.	Hormones	Immunoassay with luminometric detection	Commercial procedure	Serum, plasma	A, B, C

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2. Clinical Biochemistry Department (OKB), NBP Workplace, Obilní trh

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, urine	A, B, C
2.	Minerals	Absorption spectrophotometry	Commercial procedure	Serum, plasma, urine	A, B, C
3.	Enzymes	Absorption spectrophotometry	Commercial procedure	Serum, plasma	A, B, C
4.	Glucose	Absorption spectrophotometry	Commercial procedure	Serum, plasma	A, B
5.	Non-protein nitrogenous compounds	Absorption spectrophotometry	Commercial procedure	Serum, plasma, urine	A, B, C
6.	Proteins	Absorption spectrophotometry	Commercial procedure	Body fluids	A, B, C, D
7.	Pigments	Absorption spectrophotometry	Commercial procedure	Serum, plasma	A, B, C
813 - Allergology and Immunology Laboratory					
1.	C-reactive protein (CRP)	Immunoturbidimetry	Commercial procedure	Serum, plasma	A, B

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3. Clinical Microbiology and Immunology Department (OKMI)

Examinations:

Ordinal number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
802 – Medical Microbiology					
1.	Microbiological examination of the lower respiratory tract	Microscopy; Aerobic culture Anaerobic culture	Published procedure	Material of lower respiratory tract	A, B, C, D
2.	Microbiological examination of upper respiratory tract	Aerobic culture	Published procedure	Material of upper respiratory tract	A, B, C, D
3.	Clinically relevant antibiotic resistance screening	Aerobic culture	Published procedure	Clinical material	A, B, C, D
4.	Microbiological examination of clinical material	Aerobic culture	Published procedure	Clinical material	A, B, C, D
5.	Microbiological examination of foreign bodies	Aerobic culture	Published procedure	Foreign bodies	A, B, C, D
6.	Microbiological examination of clinical material	Microscopy; Aerobic culture; Anaerobic culture	Published procedure	Clinical material	A, B, C, D
7.	Microbiological examination of clinical material	Microscopy; Aerobic culture	Published procedure	Clinical material	A, B, D
8.	Identification of the micromycetes	Microscopy; Aerobic culture	Published procedure	Microorganism culture	A, B
9.	Identification of the microorganism	Mass spectrometry	Commercial procedure	Microorganism culture	A, B, C, D
10.	Identification of bacteria	Agglutination	Commercial procedure	Bacterial culture	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
11.	Identification of bacteria	Biochemical test	Commercial procedure	Bacterial culture	A, B, C
12.	Microbiological examination of rectal swab	Aerobic culture; Anaerobic culture	Published procedure	Stool, rectal swab, swab of stomia	A, B, C
13.	Microbiological examination of urogenital tract	Microscopy; Aerobic culture; Anaerobic culture	Published procedure	Genitourinary system material	A, B, C, D
14.	Microbiological examination of blood and primarily sterile body fluids	Aerobic culture; Anaerobic culture; Microscopy (automated)	Commercial procedure; Published procedure	Liquid clinical material	A, B, C, D
15.	Microbiological examination of primarily sterile body fluids	Aerobic culture; Anaerobic culture; Microscopy	Published procedure	Liquid clinical material	A, B, C, D
16.	Quantitative microbiological examination of urine	Aerobic culture	Published procedure	Urine	A, B, C
17.	Qualitative examination of microorganism sensitivity	Disk diffusion test	Commercial procedure; Published procedure	Microorganism culture	A, B, C, D
18.	Quantitative examination of microorganism sensitivity	Microdilution method (automated)	Commercial procedure	Microorganism culture	A, B, C, D
19.	Quantitative examination of microorganism sensitivity	Microdilution method; E-test	Commercial procedure	Microorganism culture	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
20.	Clinically relevant antibiotic resistance detection	Disc test; Biochemical test	Commercial procedure; Published procedure	Bacterial culture	A, B, C
21.	Parasitological examination for enterobiosis	Microscopy	Published procedure	Perianal imprint	A, B
22.	Parasitological examination of stool and ectoparasites	Microscopy	Published procedure	Stool, ectoparasites	A, B
23.	Examination for malaria	Microscopy	Published procedure	Clinical material	A, B, D
24.	Parasitological examination	Microscopy	Published procedure	Biological material of human origin	A, B, D
25.	Diagnostics of <i>Trichomonas vaginalis</i>	Microscopy	Published procedure	Genitourinary system material	A, B, D
26.	Detection and quantitative sensitivity testing of urogenital mycoplasmas	Aerobic culture; Biochemical identification; Microdilution method	Commercial procedure	Clinical material	A, B, C, D
27.	Detection of <i>Clostridioides difficile</i> strain antigen	Immunoassay with fluorimetric detection	Commercial procedure	Stool	A, B
28.	Detection of <i>Clostridioides difficile</i> strain toxin	Immunochromatography	Commercial procedure	Stool	A, B
29.	Detection of toxigenic gene of <i>Clostridioides difficile</i> strain	Real-Time PCR	Commercial procedure	Stool	A, B
30.	Antigens of infectious agents	Immunoassay with fluorimetric detection	Commercial procedure	Clinical material	A, B, C, D
31.	Antigens of infectious agents	Immunoassay with luminometric detection	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
32.	Antibodies against infectious agents	Immunoassay with luminometric detection	Commercial procedure	Body fluids	A, B, C, D
33.	Non-specific antibodies against <i>Treponema pallidum</i>	Immunoturbidimetry	Commercial procedure	Body fluids	A, B, D
34.	Non-specific antibodies against <i>Treponema pallidum</i>	Agglutination (manual)	Commercial procedure	Body fluids	A, B, D
35	HIV markers	Immunoassay with luminometric detection	Commercial procedure	Body fluids	A, B, D
36.	Detection of nucleic acids of infectious agents	Real-Time PCR (automated)	Commercial procedure	Body fluids	A, B, C, D
813 - Allergology and Immunology Laboratory					
1.	Autoantibodies	Indirect immunofluorescence	Commercial procedure	Body fluids	A, B, C, D
2.	Antibodies against tissue transglutaminase	Immunoassay with luminometric detection	Commercial procedure	Body fluids	A, B, D
3.	Antibodies against proteinase 3 and myeloperoxidase	Immunoassay with luminometric detection	Commercial procedure	Body fluids	A, B, D
4.	Immunophenotyping of cell populations	Flow cytometry	In-house procedure	Blood	A, B, C

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

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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

PCR 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. "