



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. 324/2025

Fakultní nemocnice Bulovka
with registered office Budínova 67/2, Libeň, 180 81 Praha 8
Company Registration No. 00064211

for the Medical Laboratory No. **8332**
Centrální laboratoře

Scope of accreditation:

NEVYPLNĚNO 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.: 498/2024 of 26/09/2024, and/or any administrative acts building upon it.

The Certificate of Accreditation is valid until: **24/07/2027**

Prague: 30/06/2025



Signed in the Czech original:
Marek Vyskočil on 30/06/2025

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. 324/2025 of 30/06/2025**

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

Fakultní nemocnice Bulovka
CAB Number 8332, Centrální laboratoře
Budínova 67/2, Libeň, 180 81 Praha 8

Medical laboratory locations:

- | | | |
|----|--|--|
| 1. | Oddělení klinické biochemie | Budova 8, Budínova 67/2, 180 81 Praha 8 |
| 2. | Patologicko - anatomické oddělení | Budova 17, Budínova 67/2, 180 81 Praha 8 |
| 3. | Oddělení klinické hematologie a transfúze | Budova 8, Budínova 67/2, 180 81 Praha 8 |
| 4. | Oddělení klinické mikrobiologie | Budova 8, Budínova 67/2, 180 81 Praha 8 |
| 5. | Oddělení klinické imunologie a virologie | Budova 8, Budínova 67/2, 180 81 Praha 8 |
| 6. | Laboratoř lékařské genetiky | Budova 8, Budínova 67/2, 180 81 Praha 8 |
| 7. | Centrální odběrové místo (COM2) | Budova 2, Budínova 67/2, 180 81 Praha 8 |
| 8. | Centrální odběrové místo (COM8) | Budova 8, Budínova 67/2, 180 81 Praha 8 |

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://bulovka.cz/kliniky-a-oddeleni/centralni-laboratore>.

1. Oddělení klinické biochemie

Examinations:

Ordinal Number	Analyte/parameter/diagnostics	Principle of examination	Identification of method 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	Body fluids	A, B, C, D
4.	Saccharides	Absorption spectrophotometry	Commercial procedure	Serum, plasma, urine, cerebrospinal fluid	A, B, C
5.	Proteins	Absorption spectrophotometry	Commercial procedure	Serum, plasma	A, B, C
6.	Lipids	Absorption spectrophotometry	Commercial procedure	Serum, plasma	A, B, C
7.	Non-protein nitrogenous compounds	Absorption spectrophotometry	Commercial procedure	Serum, plasma, urine	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.	Tumor markers	Immunoassay with luminometric detection	Commercial procedure	Serum, plasma	A, B, C
813 - Allergology and Immunology Laboratory					
1.	Proteins	Immunoturbidimetry	Commercial procedure	Serum, plasma	A, B, C
815 - Nuclear Medicine Laboratory					
1.	Hormones	Immunoassay with luminometric detection	Commercial procedure	Serum, plasma	A, B, C

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2. Patologicko - anatomické oddělení

Examinations:

Ordinal Number	Analyte/parameter/diagnostics	Principle of examination	Identification of method procedure/equipment	Examined material	Degrees of freedom ¹
823 - Pathology Laboratory					
1.	Histological examination and diagnostics	Microscopy	Published procedure	Tissue	A, B
2.	Cytological examination and diagnostics	Microscopy	Published procedure	Cells	A, B
3.	Intraoperative histological examination and diagnostics	Microscopy	Published procedure	Tissue	A, B
4.	Immunohistochemical and immunocytochemical examination of antigens	Microscopy	Published procedure	Tissue, cells	A, B, C

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3. Oddělení klinické hematologie a transfúze

Examinations:

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of method procedure/equipment	Examined material	Degrees of freedom ¹
222 - Transfusion Medicine					
1.	Blood type	Agglutination in test tubes (manual)	Commercial procedure	Blood	A, B
2.	Blood type	Gel column agglutination (automatic)	Commercial procedure	Blood	A, B
3.	Screening of irregular anti-erythrocyte antibodies	Gel column agglutination (manual)	Commercial procedure	Plasma, serum	A, B
4.	Screening of irregular anti-erythrocyte antibodies	Gel column agglutination (automatic)	Commercial procedure	Plasma, serum	A, B
818 - Haematology Laboratory					
1.	Blood count with a five-part differential leukocyte count	Flow cytometry; Impedance method; Photometry; Calculations	Commercial procedure	Blood	A, B, C
2.	Reticulocytes	Flow cytometry; Calculations	Commercial procedure	Blood	A, B
3.	Peripheral blood smear test	Microscopy	Commercial procedure	Blood	A, B, C
4.	Peripheral blood smear test	Digital Microscopy	Commercial procedure	Blood	A, B, C
5.	Prothrombin test	Coagulation method with mechanical detection of coagulum; Calculation	Commercial procedure	Plasma	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
6.	Activated partial thromboplastin time	Coagulation method with mechanical detection of coagulum; Calculation	Commercial procedure	Plasma	A, B
7.	Fibrinogen	Coagulation method with mechanical detection of coagulum;	Commercial procedure	Plasma	A, B
8.	Antithrombin	Absorption spectrophotometry	Commercial procedure	Plasma	A, B
9.	D-Dimers	Immunoassay with turbidimetric detection	Commercial procedure	Plasma	A, B

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4. Oddělení klinické mikrobiologie

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 upper respiratory tract	Aerobic culture	Published procedure	Material of upper respiratory tract	A, B, D
2.	Microbiological examination of the lower respiratory tract	Microscopy; Aerobic culture	Published procedure	Material of lower respiratory tract	A, B, D
3.	Microbiological examination of rectal swab	Aerobic culture	Published procedure	Rectal and stoma swab, stool	A, B
4.	Semi-quantitative microbiological examination of urine	Microscopy Aerobic culture	Published procedure	Urine	A, B
5.	Microbiological examination of blood and primarily sterile body fluids	Microscopy; Aerobic culture; Anaerobic culture	Commercial procedure	Liquid clinical material	A, B, D
6.	Microbiological examination of clinical material	Microscopy; Aerobic culture; Anaerobic culture	Published procedure	Liquid clinical material	A, B, D
7.	Microbiological examination of clinical material	Microscopy; Aerobic culture; Anaerobic culture	Published procedure	Pus	A, B
8.	Microbiological examination of clinical material	Aerobic culture	Published procedure	Clinical material	A, B, D
9.	Microbiological examination of clinical material	Aerobic culture	Published procedure	Clinical material	A, B, 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.	Microbiological examination of urogenital tract	Microscopy; Aerobic culture	Published procedure	Genitourinary system material	A, B, D
11.	Microbiological examination of foreign bodies	Aerobic culture	Published procedure	Foreign bodies	A, B, D
12.	Mycobacterial examination	Fluorescence microscopy; Aerobic culture	Published procedure	Clinical material	A, B, D
13.	Identification of the microorganism	Mass spectrometry	Commercial procedure	Bacterial culture, yeast culture	A, B
14.	Antibiotic susceptibility testing	Disk diffusion test	Published procedure	Bacterial culture, yeast culture	A, B
15.	Quantitative examination of microorganism sensitivity	E-test	Published procedure	Bacterial culture, yeast culture	A, B
16.	Parasitological examination of stool	Microscopy	Published procedure	Stool	A, B
17.	Examination for malaria	Microscopy	Published procedure	Blood	A, B
18.	Examination for malaria	Immunochromatography	Published procedure	Blood	A, B
19.	Detection of nucleic acids of infectious agents	Real-Time PCR	Commercial procedure	Clinical material	A, B, C, D
20.	Detection of nucleic acids of infectious agents	Real-Time PCR	Commercial procedure	Body fluids	A, B, C, D

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5. Oddělení klinické imunologie a virologie

Examinations:

Ordinal Number	Analyte/parameter/diagnostics	Principle of examination	Identification of method procedure/equipment	Examined material	Degrees of freedom ¹
813 - Allergology and Immunology Laboratory					
1.	Immunoglobulins	Immunonephelometry	Commercial procedure	Body fluids	A, B, C, D
2.	Specific proteins	Immunonephelometry	Commercial procedure	Body fluids	A, B, C, D
3.	Immunophenotyping of cell populations	Flow cytometry	Commercial procedure	Blood	A, B, C
4.	Autoantibodies	Indirect immunofluorescence	Commercial procedure	Body fluids	A, B, C, D
5.	Autoantibodies	Immunoassay with luminometric detection	Commercial procedure	Body fluids	A, B, C, D
6.	Immunoglobulin E	Immunoassay with fluorimetric detection	Commercial procedure	Body fluids	A, B, D
7.	Specific IgE	Immunoassay with fluorimetric detection	Commercial procedure	Body fluids	A, B, D
802 – Medical Microbiology					
1.	Antibodies against infectious agents	Immunoassay with luminometric detection	Commercial procedure	Serum, plasma	A, B, C
2.	Antibodies against infectious agents	Immunoassay with luminometric detection	Commercial procedure	Serum, plasma	A, B, C
3.	Antigens of infectious agents	Immunoassay with luminometric detection	Commercial procedure	Serum, plasma	A, B, C
4.	HIV markers (screening)	Immunoassay with luminometric detection	Commercial procedure	Serum, plasma	A, B
5.	Antibodies against infectious agents	Immunoassay with photometric detection	Commercial procedure	Blood, cerebrospinal fluid, synovial fluid	A, B, C

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6. Laboratoř lékařské genetiky

Examinations:

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of method procedure/equipment	Examined material	Degrees of freedom ¹
816 – Medical Genetics Laboratory					
1.	Examination of germline genome variants	Real-Time PCR	LLG_SOPL_001 v.1; LLG_SOPA_001 v.1; LLG_SOPA_002 v.1; LLG_PI_006 v.1; LLG_PI_007 v.1; LLG_PI_009 v.1; LLG_PI_010 v.1; CFXConnect/ 96TM	Peripheral blood	-
2.	Examination of somatic genome variants	Real-Time PCR	LLG_SOPL_001 v.1; LLG_SOPA_003 v.1; LLG_PI_012 v.1; CFXConnect/ 96TM	Peripheral blood	-

Specification of the scope of accreditation:

Field Nr./ Ordinal Number	Detailed information on activities within the scope of accreditation
816/1	Thrombophilic mutations: FV Leiden (c. 1601G>A, p. R534Q); FII (G20210A)
816/2	JAK2 (p. V617F)

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- 7. **Centrální odběrové místo (COM2)**
- 8. **Centrální odběrové místo (COM8)**

Primary sample collection:

Ordinal Number	Sample collection technique	Identification of sample collection procedure	Collected material	Degrees of freedom ¹
1.	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

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. "