



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. **607/2025**

Fakultní nemocnice Ostrava
with registered office 17. listopadu 1790/5, 708 52 Ostrava - Poruba
Company Registration No. 00843989

for the Medical Laboratory No. **8026**
Institute of Laboratory Medicine

Scope of accreditation:

Examinations in the field of clinical biochemistry, haematology, clinical pharmacology, 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.: 347/2024 of 15/07/2024, and/or any administrative acts building upon it.

The Certificate of Accreditation is valid until: **15/07/2029**

Prague: 24/11/2025



Signed in the Czech original:
Milena Lochmanová on 24/11/2025

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. 607/2025 of 24/11/2025**

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

Fakultní nemocnice Ostrava
CAB Number 8026, Institute of Laboratory Medicine
17. listopadu 1790/5, 708 52 Ostrava - Poruba

Medical laboratory locations:

- | | |
|---|---|
| 1. Department of Clinical Biochemistry (OKB) | 17. listopadu 1790/5, 708 52 Ostrava - Poruba |
| 2. Department of Clinical Hematology (OKH) | 17. listopadu 1790/5, 708 52 Ostrava - Poruba |
| 3. Department of Clinical Pharmacology (OKF) | 17. listopadu 1790/5, 708 52 Ostrava - Poruba |
| 4. Department of Microbiological Methods (ÚMM) | 17. listopadu 1790/5, 708 52 Ostrava - Poruba |

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://fnostrava.slp.blue/verejna-prirucka/stranka/seznam-cinnosti-v-ramci-fra>*

1. Department of Clinical Biochemistry (OKB)

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.	Non-protein nitrogenous compounds	Absorption spectrophotometry	Commercial procedure	Serum, plasma, urine	A, B, C
4.	Proteins	Absorption spectrophotometry	Commercial procedure	Body fluids	A, B, C, D
5.	Glucose	Absorption spectrophotometry	Commercial procedure	Serum, plasma	A, B
6.	Lipids	Absorption spectrophotometry	Commercial procedure	Serum, plasma	A, B, C
7.	Pigments	Absorption spectrophotometry	Commercial procedure	Serum, plasma	A, B, C
8.	Enzymes	Absorption spectrophotometry	Commercial procedure	Serum, plasma	A, B, C
9.	Acid-base balance	Potentiometry; Amperometry	Commercial procedure	Blood	A, B

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Ordinal Number	Analyte/parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
10.	Proteins	Immunonephelometry	Commercial procedure	Body fluids	A, B, C, D
11.	Markers for congenital disorders risk calculation	Fluorescence immunoassay	Commercial procedure	Serum	A, B, C
12.	Glycated haemoglobin (HbA1c)	High-Performance Liquid Chromatography	Commercial procedure	Blood	A, B
13.	Calculated parameters	Calculation	Published procedure	Urine	A, B
14.	Osmolality	Cryoscopy	Commercial procedure	Serum, plasma, urine	A, B
15.	Cardiac markers	Immunoassay with luminometric detection	Commercial procedure	Serum, plasma	A, B, C
16.	Proteins	Electrophoresis	Commercial procedure	Body fluids	A, B, C, D
813 - Allergology and Immunology Laboratory					
1.	Specific proteins	Immunonephelometry	Commercial procedure	Body fluids	A, B, C, D
2.	Immunoglobulins	Immunonephelometry	Commercial procedure	Body fluids	A, B, C, D
3.	C-reactive protein (CRP)	Immunoturbidimetry	Commercial procedure	Serum, plasma	A, B
4.	Interleukin-6 (IL-6)	Immunoassay with luminometric detection	Commercial procedure	Serum, plasma	A, B
5.	Autoantibodies	Immunoassay with photometric detection	Commercial procedure	Body fluids	A, B, C, D
6.	Autoantibodies	Immunoassay with luminometric detection	Commercial procedure	Body fluids	A, B, C, D
7.	Immunophenotyping of cell populations	Flow cytometry	Commercial procedure	Blood	A, B, C
8.	Immunoglobulins	Immunoassay with luminometric detection	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
815 - Nuclear Medicine Laboratory					
1.	Hormones	Immunoassay with luminometric detection	Commercial procedure	Serum, plasma	A, B, C
2.	Tumour markers	Immunoassay with luminometric detection	Commercial procedure	Serum, plasma	A, B, C
3.	Autoantibodies	Immunoassay with luminometric detection	Commercial procedure	Serum, plasma	A, B, C

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2. Department of Clinical Hematology (OKH)

Examinations:

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
818 - Haematology Laboratory					
1.	Blood count	Flow cytometry; Impedance method; Photometry; Calculations	Commercial procedure	Blood	A, B
2.	Prothrombin test	Coagulation method with optical detection of coagulum; Calculations	Commercial procedure	Plasma	A, B
3.	Activated partial thromboplastin time	Coagulation method with optical detection of coagulum; Calculations	Commercial procedure	Plasma	A, B
4.	Fibrinogen	Coagulation method with optical detection of coagulum	Commercial procedure	Plasma	A, B
5.	Antithrombin	Chromogenic method	Commercial procedure	Plasma	A, B
6.	D-dimers	Immunoassay with turbidimetric detection	Commercial procedure	Plasma	A, B

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3. Department of Clinical Pharmacology (OKF)

Examinations:

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
812 – Laboratory for Pharmacology and Toxicology of Pharmaceuticals					
1.	Drugs	Liquid chromatography with mass detection	In-house procedure; Published procedure	Body fluids	A, B, C, D

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4. Department of Microbiological Methods (ÚMM)

Examinations:

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

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.

"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."