



**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. <b>Department of Clinical Biochemistry (OKB)</b>   | 17. listopadu 1790/5, 708 52 Ostrava - Poruba |
| 2. <b>Department of Clinical Hematology (OKH)</b>     | 17. listopadu 1790/5, 708 52 Ostrava - Poruba |
| 3. <b>Department of Clinical Pharmacology (OKF)</b>   | 17. listopadu 1790/5, 708 52 Ostrava - Poruba |
| 4. <b>Department of Microbiological Methods (ÚMM)</b> | 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 <sup>1</sup> |
|------------------------------------|-----------------------------------|------------------------------|---------------------------------------|----------------------|---------------------------------|
| <b>801 – Clinical Biochemistry</b> |                                   |                              |                                       |                      |                                 |
| 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 <sup>1</sup> |
|----------------|---|---|---------------------------------------|----------------------|---------------------------------|
| 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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|--|-------------------------------|---|---------------------------------------|-------------------|---------------------------------|
| <b>815 - Nuclear Medicine Laboratory</b> |                               |   |                                       |                   |                                 |
| 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 <sup>1</sup> |
|-------------------------------------|---------------------------------------|--|---------------------------------------|-------------------|---------------------------------|
| <b>818 - Haematology Laboratory</b> |                                       |  |                                       |                   |                                 |
| 1.                                  | Blood count                           | Flow cytometry;<br>Impedance method;<br>Photometry;<br>Calculations    | Commercial procedure                  | Blood             | A, B                            |
| 2.                                  | Prothrombin test                      | Coagulation method with optical detection of coagulum;<br>Calculations | Commercial procedure                  | Plasma            | A, B                            |
| 3.                                  | Activated partial thromboplastin time | Coagulation method with optical detection of coagulum;<br>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 <sup>1</sup> |
|--|--------------------------------|---|--|-------------------|---------------------------------|
| <b>812 – Laboratory for Pharmacology and Toxicology of Pharmaceuticals</b> |                                |   |  |                   |                                 |
| 1.   | Drugs                          | Liquid chromatography with mass detection | In-house procedure;<br>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 <sup>1</sup> |
|-----------------------------------|---|---|---------------------------------------|-------------------|---------------------------------|
| <b>802 – Medical Microbiology</b> |   |   |                                       |                   |                                 |
| 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:**

<sup>1</sup> 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.