**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. **478/2025**

**Fakultní nemocnice Olomouc**
**with registered office Zdravotníků 248/7, 779 00 Olomouc**
**Company Registration No. 00098892**

for the Medical Laboratory No. **8203**
Laboratories of the Hemato-Oncology Clinic

Scope of accreditation:

Examinations in the fields of haematology, cytogenetics and molecular genetics, 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.: 258/2024 of 04/06/2024, and/or any administrative acts building upon it.

The Certificate of Accreditation is valid until: **22/09/2030**

Prague: 22/09/2025

Signed in the Czech original:
Milena Lochmanová on 22/09/2025

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. 478/2025 of 22/09/2025**

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

**Fakultní nemocnice Olomouc**
CAB Number 8203, Laboratories of the Hemato-Oncology Clinic
Zdravotníků 248/7, 779 00 Olomouc

*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://hok.fnol.cz/dokumenty-laboratori-hok.*

## Examinations:

| Ordinal Number | Analyte/ parameter/diagnostics | Principle of examination | Identification of procedure/equipment | Examined material | Degrees of freedom[1] |
|---|---|---|---|---|---|
| **813 - Allergology and Immunology Laboratory** | | | | | |
| 1. | Immunophenotyping of cell populations | Flow cytometry | In-house procedure | Peripheral blood | A, B |
| **816 – Medical Genetics Laboratory** | | | | | |
| 1. | Detection of chromosomal rearrangements | Nested RT-PCR | Published procedure | Biological material containing human nucleic acid | A, B, C, D |
| 2. | Examination of somatic genome variants | Sanger sequencing | Published procedure; In-house procedure | Biological material containing human nucleic acid | A, B, C, D |
| 3. | Examination of somatic genome variants | PCR with fragment analysis | Published procedure; In-house procedure | Biological material containing human nucleic acid | A, B, C, D |
| 4. | Thrombophilic mutations | Real-Time PCR | Commercial procedure | Biological material containing human nucleic acid | A, B, C, D |
| 5. | Examination of germline genome variants | MLPA | Published procedure; In-house procedure | Biological material containing human nucleic acid | A, B, C, D |
| 6. | Examination of somatic genome variants | NGS-MPS | Commercial procedure | Biological material containing human nucleic acid | A, B, C, D |
| 7. | Examination of germline genome variants | NGS-MPS | Commercial procedure | Biological material containing human nucleic acid | A, B, C, D |
| 8. | HLA system examination | PCR-SSP | Commercial procedure | Biological material containing human nucleic acid | 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] |
|---|---|---|---|---|---|
| 9. | Examination of somatic genome variants | PCR with electrophoretic detection | Commercial procedure | Biological material containing human nucleic acid | A, B, C, D |
| 10. | Gene expression | Real-Time RT-PCR | Published procedure; In-house procedure | Biological material containing RNA | A, B, C, D |
| 11. | Examination of tumor karyotype | Conventional cytogenetic analysis | Published procedure | Peripheral blood, bone marrow, lymph node, spleen and other tumor tissues | A, B |
| 12. | Examination of chromosomal aberrations | FISH | Published procedure | Peripheral blood, bone marrow, lymph node, spleen and other tumor tissues | A, B |
| 13. | Examination of unbalanced chromosomal aberrations | aCGH | Commercial procedure | Peripheral blood, bone marrow, lymph node, spleen and other tumor tissues | 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 |
| 2. | Reticulocytes | Flow cytometry; Calculations | Commercial procedure | Blood | A, B |
| 3. | Peripheral blood smear test | Microscopy | Published procedure | Blood | A, B |
| 4. | Peripheral blood smear test | Digital microscopy | Published 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] |
|---|---|---|---|---|---|
| 5. | Prothrombin test | Coagulation method with optical detection of coagulum;<br>Calculation | Commercial procedure | Plasma | A, B |
| 6. | Activated partial thromboplastin time | Coagulation method with optical detection of coagulum;<br>Calculation | Commercial procedure | Plasma | A, B |
| 7. | Fibrinogen | Coagulation method with optical detection of coagulum | Commercial procedure | Plasma | A, B |
| 8. | Antithrombin | Chromogenic method | Commercial procedure | Plasma | A, B |
| 9. | D-dimers | Immunoassay with optic detection | Commercial procedure | Plasma | 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

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.

| | |
|---|---|
| FISH | Fluorescence *in situ* Hybridization |
| NGS-MPS | Next Generation Sequencing - Massively Parallel Sequencing |
| PCR | Polymerase Chain Reaction |
| Real-Time PCR | Polymerase Chain Reaction in Real Time |
| RT-PCR | Reverse Transcription Polymerase Chain Reaction |
| PCR-SSP | Polymerase Chain Reaction with Sequence-Specific Primers |
| Nested RT-PCR | Multiplexá Reverse Transcription Polymerase Chain Reaction |
| aCGH | Oligonucleotide array Comparative Genomic Hybridization |

*"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. "*