



EA MLA Signatory
Český institut pro akreditaci, o.p.s.
Olšanská 54/3, 130 00 Praha 3

issues

according to section 16 of Act No. 22/1997 Coll., on technical requirements for products, as amended

CERTIFICATE OF ACCREDITATION

No. 258/2024

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. 2:2013


In its activities performed within the scope and for the period of validity of this Certificate, the Conformity Assessment 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.: 85/2023 of 24. 2. 2023, or any administrative acts building upon it.

The Certificate of Accreditation is valid until: **25. 9. 2025**

Prague: 4. 6. 2024




Milena Lochmanová
Director of the Department
of Medical Laboratories
Czech Accreditation Institute

**The Appendix is an integral part of
Certificate of Accreditation No. 258/2024 of 04/06/2024**

Accredited entity according to ČSN EN ISO 15189 ed. 2:2013:

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 - Allergy 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 nucleic acid	A, B, C, D
2.	Examination of somatic genome variants	Sanger sequencing	Published procedure; In-house procedure	Biological material containing nucleic acid	A, B, C, D
3.	Examination of somatic genome variants	PCR with fragment analysis	Published procedure; In-house procedure	Biological material containing nucleic acid	A, B, C, D
4.	Thrombophilic mutations	Real-Time PCR	Commercial procedure	Biological material containing nucleic acid	A, B, C, D
5.	Examination of germline genome variants	MLPA	Published procedure; In-house procedure	Biological material containing nucleic acid	A, B, C, D
6.	Examination of somatic genome variants	NGS-MPS	Commercial procedure	Biological material containing nucleic acid	A, B, C, D
7.	HLA system examination	PCR-SSP	Commercial procedure	Biological material containing nucleic acid	A, B, C, D
8.	Examination of somatic genome variants	PCR with electrophoretic detection	Published procedure; In-house procedure	Biological material containing nucleic acid	A, B, C, D



**The Appendix is an integral part of
Certificate of Accreditation No. 258/2024 of 04/06/2024**

Accredited entity according to ČSN EN ISO 15189 ed. 2:2013:

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

Ordinal Number	Analyte/parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
9.	Gene expression	Real-Time RT-PCR	Commercial procedure; In-house procedure	Biological material containing RNA	A, B, C, D
10.	Examination of tumor karyotype	Conventional cytogenetic analysis	Published procedure	Peripheral blood, bone marrow, lymph node, spleen and other tumor tissues	A, B
11.	Examination of chromosomal aberrations	FISH	Published procedure	Peripheral blood, bone marrow, lymph node, spleen and other tumor tissues	A, B
12.	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	Commercial procedure	Blood	A, B
4.	Peripheral blood smear test	Digital microscopy	Commercial procedure	Blood	A, B
5.	Prothrombin test	Coagulation method with optical detection of coagulum; Calculation	Commercial procedure	Plasma	A, B
6.	Activated partial thromboplastin time	Coagulation method with mechanical detection of coagulum; Calculation	Commercial procedure	Plasma	A, B

**The Appendix is an integral part of
Certificate of Accreditation No. 258/2024 of 04/06/2024**

Accredited entity according to ČSN EN ISO 15189 ed. 2:2013:

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

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
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

If no degree of freedom is specified, the laboratory cannot apply a flexible approach to the scope of accreditation for this examination.

FISH	Fluorescence <i>in situ</i> 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."

