



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. **581/2025**

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

for the Medical Laboratory No. **8230**
Blood Center Laboratories

Scope of accreditation:

Laboratory examination in the field of immunohematology and transfusion service including shared examination 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.: 451/2024 of 03/09/2024, and/or any administrative acts building upon it.

The Certificate of Accreditation is valid until: **13/11/2030**

Prague: 13/11/2025



Signed in the Czech original:
Milena Lochmanová on 13/11/2025

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. 581/2025 of 13/11/2025**

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

Fakultní nemocnice Ostrava
CAB Number 8230, Blood Center Laboratories
17. listopadu 1790/5, 708 52 Ostrava - Poruba

Medical laboratory locations:

1. **Immunohematology Section** 17. listopadu 1790/5, 708 52 Ostrava – Poruba
2. **HLA, DNA Laboratory** 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://www.fno.cz/krevni-centrum/zabezpecovani-kvality>

1. Immunohematology Section

Examinations:

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
222 - Transfusion Medicine					
1.	Blood type	Agglutination in test tube	Commercial procedure	Blood	A, B
2.	Blood type	Gel column agglutination	Commercial procedure	Blood	A, B
3.	Screening of anti-erythrocyte antibodies	Gel column agglutination (manual)	Commercial procedure	Plasma, serum	A, B
4.	Screening of anti-erythrocyte antibodies	Gel column agglutination	Commercial procedure	Plasma	A, B

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Fakultní nemocnice Ostrava
CAB Number 8230, Blood Center Laboratories
17. listopadu 1790/5, 708 52 Ostrava - Poruba

2. HLA, DNA Laboratory

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.	HLA system examination	PCR-SSP	Commercial procedure	Biological material containing nuclear DNA	A, B, C, D
2.	HLA system examination	PCR-SSP with end-point fluorescence detection	Commercial procedure	Biological material containing nuclear DNA	A, B, C, D
3.	HLA system examination	Real-Time PCR	Commercial procedure	Biological material containing nuclear DNA	A, B, C, D
4.	Anti-HLA antibodies examination	xMAP technology	Commercial procedure	Serum	A, B, C

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.

HLA	Human leukocyte antigens system
PCR-SSP	Polymerase chain reaction with sequence specific primers
Real-Time PCR	Real-time polymerase chain reaction
xMAP	Methodology for multiplex determination of analytes (here anti-HLA antibodies) using microparticles with diagnostics as a solid phase

"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. "