



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. 659/2025

Fakultní nemocnice u sv. Anny v Brně
with registered office Pekařská 664/53, 602 00 Brno
Company Registration No. 00159816

for the Medical Laboratory No. **8053**
Laboratories of Department of Clinical Haematology

Scope of accreditation:

Laboratory examinations in the field of haematology 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.: 609/2024 of 15/11/2024, and/or any administrative acts building upon it.

The Certificate of Accreditation is valid until: **18/12/2030**

Prague: 18/12/2025



Signed in the Czech original:
Milena Lochmanová on 18/12/2025

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. 659/2025 of 18/12/2025**

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

Fakultní nemocnice u sv. Anny v Brně
CAB Number 8053, Laboratories of Department of Clinical Haematology
Pekařská 664/53, 602 00 Brno

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.fnusa.cz/pro-pacienty-a-navstevy/zdravotnicka-pracoviste/oddeleni-klinicke-hematologie/>

Examinations:

Ordinal Number	Analyte/parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
818 - Haematology Laboratory					
1.	Activated partial thromboplastin time	Coagulation method with optical detection of coagulum; Calculations	Commercial procedure	Plasma	A, B
2.	Antithrombin	Chromogenic method	Commercial procedure	Plasma	A, B
3.	D-dimers	Immunoassay with fluorimetric detection	Commercial procedure	Plasma	A, B
4.	Peripheral blood smear test	Microscopy	Commercial procedure	Blood	A, B
5.	Peripheral blood smear test	Digital microscopy	Commercial procedure	Blood	A, B
6.	Fibrinogen	Coagulation method with optical detection of coagulum	Commercial procedure	Plasma	A, B
7.	Blood count with a five-part differential leukocyte count	Flow cytometry; Impedance method; Photometry; Calculations	Commercial procedure	Blood	A, B, C
8.	Prothrombin test	Coagulation method with optical detection of coagulum; Calculations	Commercial procedure	Plasma	A, B

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CAB Number 8053, Laboratories of Department of Clinical Haematology
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Ordinal Number	Analyte/parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
9.	Reticulocytes	Flow cytometry; Calculations	Commercial procedure	Blood	A, B
10.	Erythrocyte sedimentation rate	Optical detection	Commercial procedure	Blood	A, B
11.	von Willebrand factor	Immunoassay with fluorimetric detection	Commercial procedure	Plasma	A, B
12.	Haemocoagulation factors - the intrinsic pathway	Coagulation method with optical detection of coagulum;	Commercial procedure	Plasma	A, B, C
13.	D-dimers	Immunoassay with turbidimetric 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.

"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."