

EA MLA Signatory  
Český institut pro akreditaci, o.p.s.  
Hájkova 2747/22, Žižkov, 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. 609/2024

**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. 2:2013

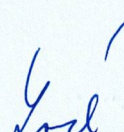
In its activities performed within the scope and for the period of validity of this Certificate, the Conformity Assessment Body is entitled to refer to this Certificate, provided that the accreditation is not suspended and the Accredited Body meets the specified accreditation requirements in accordance 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.: 76/2021 of 21/01/2021, or any administrative acts building upon it.

The Certificate of Accreditation is valid until: **21/01/2026**

Prague: 15/11/2024



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



**The Appendix is an integral part of  
Certificate of Accreditation No. 609/2024 of 15/11/2024**

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

**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/pracoviste/okh-zakladni-informace-2/okh-dalsi-informace/#toggle-id-5>*

**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.	Activated partial thromboplastin time	Coagulation method with optical detection of coagulum; Calculation	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; Digital microscopy	Commercial procedure	Blood	A, B
5.	Fibrinogen	Coagulation method with optical detection of coagulum; Calculation	Commercial procedure	Plasma	A, B
6.	Blood count with a five-part differential leukocyte count	Flow cytometry; Impedance method; Photometry; Calculations	Commercial procedure	Blood	A, B
7.	Prothrombin test	Coagulation method with optical detection of coagulum; Calculation	Commercial procedure	Plasma	A, B
8.	Reticulocytes	Flow cytometry; Calculations	Commercial procedure	Blood	A, B
9.	Erythrocyte sedimentation rate	Optical detection	Commercial procedure	Blood	A, B

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Pekařská 664/53, 602 00 Brno

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom <sup>1</sup>
10.	von Willebrand factor	Immunoassay with fluorimetric detection	Commercial procedure	Plasma	A, B
11.	Haemocoagulation factors in the intrinsic pathway	Coagulation method with optical detection of coagulum;	Commercial procedure	Plasma	A, B
12.	D-dimers	Immunoassay with turbidimetric detection	Commercial procedure	Plasma	A, B

**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

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."*

