



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. 387/2025

Masarykův onkologický ústav with registered office Žlutý kopec 543/7, 656 53 Brno Company Registration No. 00209805

for the Medical Laboratory No. **8084** Department of Laboratory Medicine

Scope of accreditation:

Examinations in the field of clinical biochemistry, haematology, immunohaematology and transfusion service, including shared examinations (with a focus on oncology) 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.: 310/2024 of 02/07/2024, and/or any administrative acts building upon it.

The Certificate of Accreditation is valid until: 02/02/2028

Prague: 25/07/2025





Signed in the Czech original: Milena Lochmanová on 25/07/2025

> 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. 387/2025 of 25/07/2025

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

Masarykův onkologický ústav

CAB Number 8084, Department of Laboratory Medicine Žlutý kopec 543/7, 656 53 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 www.mou.cz/oddeleni-laboratorni-mediciny/t1364

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	Gel column agglutination	Commercial procedure	Blood, plasma	A, B				
2.	Examination of compatibility	Gel column agglutination	Commercial procedure	Blood, plasma	A, B				
3.	Screening of anti- erythrocyte antibodies	Gel column agglutination	Commercial procedure	Plasma	A, B				
801 – Clinical Biochemistry									
1.	Glucose	Absorption spectrophotometry	Commercial procedure	Serum, plasma	A, B				
2.	Total bilirubin	Absorption spectrophotometry	Commercial procedure	Serum, plasma	A, B				
3	Troponin T	Immunoassay with luminometric detection	Commercial procedure	Serum, plasma	A, B				
4	Total protein	Turbidimetry	Commercial procedure	Urine	A, B				
5.	Ferritin	Immunoassay with luminometric detection	Commercial procedure	Serum, plasma	A, B				
6.	Enzymes	Absorption spectrophotometry	Commercial procedure	Serum, plasma	A, B, C				
7.	Proteins	Absorption spectrophotometry	Commercial procedure	Serum, plasma	A, B, C				
8.	Lipids	Absorption spectrophotometry	Commercial procedure	Serum, plasma	A, B, C				
9.	Non-protein nitrogenous compounds	Absorption spectrophotometry	Commercial procedure	Serum, plasma	A, B, C				

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Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹				
10.	Minerals	Potentiometry	Commercial procedure	Serum, plasma	A, B, C				
11.	Minerals	Absorption spectrophotometry	Commercial procedure	Serum, plasma	A, B, C				
813 - Allergology and Immunology Laboratory									
1.	C-reactive protein (CRP)	Immunoturbidimetry	Commercial procedure	Serum, plasma	A, B				
2.	Immunoglobulins	Immunoturbidimetry	Commercial procedure	Serum, plasma	A, B, C				
815 - Nuclear Medicine Laboratory									
1.	Tumour markers	Immunoassay with luminometric detection	Commercial procedure	Serum	A, B, C				
	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.	Peripheral blood smear test	Microscopy	Published procedure	Blood	A, B				
3.	Peripheral blood smear test	Digital microscopy	Commercial procedure	Blood	A, B				
4.	Prothrombin test	Coagulation method with optical detection of coagulum; Calculation	Commercial procedure	Plasma	A, B				
5.	Activated partial thromboplastin time	Coagulation method with optical detection of coagulum; Calculation	Commercial procedure	Plasma	A, B				
6.	Fibrinogen	Coagulation method with optical detection of coagulum	Commercial procedure	Plasma	A, B				

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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.

[&]quot;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."