



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. 464/2025

Nemocnice Na Homolce
with registered office Roentgenova 37/2, 150 30 Praha 5, Motol
Company Registration No. 00023884

for the Medical Laboratory No. **8126**
Clinical Biochemistry, Hematology and Immunology

Scope of accreditation:

Laboratory diagnostics in the fields of clinical biochemistry including the shared examinations, hematology, allergology and clinical immunology, molecular genetics, immunohematology and transfusion service, including the collection of primary samples 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.: 239/2024 of 29/05/2024, and/or any administrative acts building upon it.

The Certificate of Accreditation is valid until: 29/05/2029

Prague: 15/09/2025



Signed in the Czech original:
Marek Vyskočil on 15/09/2025

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. 464/2025 of 15/09/2025**

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

Nemocnice Na Homolce
CAB Number 8126, Clinical Biochemistry, Hematology and Immunology
Roentgenova 37/2, 150 30 Praha 5, Motol

Medical laboratory locations:

- | | | |
|----|---|-------------------------------------|
| 1. | Clinical Biochemistry and Immunoanalysis | Roentgenova 37/2, 150 30 Praha 5 |
| 2. | Haematology and Blood Bank | Roentgenova 37/2, 150 30 Praha 5 |
| 3. | Clinical Immunology | Roentgenova 37/2, 150 30 Praha 5 |
| 4. | Laboratory of Molecular Diagnostics | Pod Kotlářkou 34/34, 150 30 Praha 5 |

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.homolka.cz/nase-oddeleni/11635-diagnosticky-program/11635-odd-klinicke-biochemie-hematologie-a-imunologie-okbhi/11814-laboratorni-prirucka-okbhi/>*

1. Clinical Biochemistry and Immunoanalysis

Examinations:

Ordinal Number	Analyte/parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
801 – Clinical Biochemistry					
1.	Minerals	Potentiometry	Commercial procedure	Plasma	A, B, C
2.	Non-protein nitrogenous substances	Absorption spectrophotometry	Commercial procedure	Plasma	A, B, C
3.	Enzymes	Absorption spectrophotometry	Commercial procedure	Plasma	A, B, C
4.	Minerals	Absorption spectrophotometry	Commercial procedure	Plasma	A, B, C
5.	Proteins	Absorption spectrophotometry	Commercial procedure	Plasma	A, B, C
6.	Saccharides	Absorption spectrophotometry	Commercial procedure	Plasma	A, B, C
7.	Lipids	Absorption spectrophotometry	Commercial procedure	Plasma	A, B, C
8.	Pigments	Absorption spectrophotometry	Commercial procedure	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
9.	Tumor markers	Immunoassay with luminometric detection	Commercial procedure	Serum	A, B, C
815 - Nuclear Medicine Laboratory					
1.	Hormones	Immunoassay with luminometric detection	Commercial procedure	Serum	A, B, C
2.	Tumor markers	Immunoassay with luminometric detection	Commercial procedure	Serum	A, B, C

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2. Haematology and Blood Bank

Examinations:

Ordinal Number	Analyte/parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
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.	Prothrombin test	Coagulation method with optical detection of coagulum; Calculations	Commercial procedure	Plasma	A, B
3.	Activated partial thromboplastin time	Coagulation method with optical detection of coagulum; Calculations	Commercial procedure	Plasma	A, B
4.	Fibrinogen	Coagulation method with optical detection of coagulum	Commercial procedure	Plasma	A, B
5.	Antithrombin	Absorption spectrophotometry	Commercial procedure	Plasma	A, B
6.	D-dimers	Immunoturbidimetry	Commercial procedure	Plasma	A, B
222 - Transfusion Medicine					
1.	Blood type	Gel column agglutination	Commercial procedure	Blood	A, B
2.	Examination of compatibility	Gel column agglutination	Commercial procedure	Plasma, serum	A, B
3.	Screening of anti-erythrocyte antibodies	Gel column agglutination	Commercial procedure	Plasma, serum	A, B

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Primary sample collection:

Ordinal Number	Sample collection technique	Identifikace postupu odběru	Identification of sample collection procedure	Degrees of freedom¹
1.	Venepuncture	Published procedure	Venous blood	A, B
2.	Capillary puncture	Published procedure	Capillary blood	A, B

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3. Clinical Immunology

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.	Immunoglobulins	Immunoturbidimetry	Commercial procedure	Serum	A, B, C
2.	Specific proteins	Immunoturbidimetry	Commercial procedure	Serum	A, B, C
3.	Immunoglobulin E	Immunoassay with fluorimetric detection	Commercial procedure	Serum	A, B
4.	Specific IgE	Immunoassay with fluorimetric detection	Commercial procedure	Serum	A, B
5.	Autoantibodies	Immunoassay with photometric detection	Commercial procedure	Serum	A, B, C
6.	Autoantibodies	Indirect immunofluorescence	Commercial procedure	Serum	A, B, C

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4. Laboratory of Molecular Diagnostics

Examinations:

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
816 – Medical Genetics Laboratory					
1.	Examination of germline genome variants	PCR - HRM	In-house procedure	Biological material containing human nucleic acid	A, B, C, D

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.

PCR – HRM Polymerase Chain Reaction - High Resolution Melting (high-resolution analysis of melting curves)

"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."