



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. 433/2025

Krajská zdravotní, a.s. - Masarykova nemocnice v Ústí nad Labem, o.z.
with registered office Sociální péče 3316/12a, Severní Terasa, 400 11 Ústí nad Labem
Company Registration No. 25488627

for the Medical Laboratory No. **8290**
Clinical Biochemistry Department

Scope of accreditation:

Laboratory examinations in the field of clinical biochemistry, including shared examinations 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.: 364/2024 of 24/07/2024, and/or any administrative acts building upon it.

The Certificate of Accreditation is valid until: **15/12/2026**

Prague: 21/08/2025



Signed in the Czech original:
Milena Lochmanová on 21/08/2025

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. 433/2025 of 21/8/2025**

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

Krajská zdravotní, a.s. - Masarykova nemocnice v Ústí nad Labem, o.z.

CAB Number 8290, Clinical Biochemistry Department
Sociální péče 3316/12a, Severní Terasa, 400 11 Ústí nad Labem

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.kzcr.eu/cz/ul/pro-pacienty/zdravotnicka-pracoviste/biochemie> .*

Examinations:

Ordinal Number	Analyte/parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
801 – Clinical Biochemistry					
1.	Non-protein nitrogenous compounds	Absorption spectrophotometry	Commercial procedure	Serum, plasma	A, B
2.	Minerals	Potentiometry	Commercial procedure	Serum, plasma	A, B, C
3.	Saccharides	Absorption spectrometry	Commercial procedure	Serum, plasma	A, B
4.	Minerals	Absorption spectrophotometry	Commercial procedure	Serum, plasma	A, B
5.	Enzymes	Absorption spectrophotometry	Commercial procedure	Body fluids	A, B, C, D
6.	Pigments	Absorption spectrophotometry	Commercial procedure	Body fluids	A, B, C, D
7.	Proteins	Absorption spectrophotometry	Commercial procedure	Body fluids	A, B, C, D
8.	Lipids	Absorption spectrophotometry	Commercial procedure	Body fluids	A, B, C, D
9.	Glycated haemoglobin	Capillary electrophoresis	Commercial procedure	Blood	A, B
10.	Cardiac markers	Immunoassay with luminometric detection	Commercial procedure	Serum, plasma	A, B
11.	Tumor markers	Immunoassay with luminometric detection	Commercial procedure	Body fluids	A, B, C, D
813 - Allergology and Immunology Laboratory					
1.	Specific proteins	Immunoturbidimetry	Commercial procedure	Serum, plasma	A, B, C

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CAB Number 8290, Clinical Biochemistry Department
Sociální péče 3316/12a, Severní Terasa, 400 11 Ústí nad Labem

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
815 - Nuclear Medicine Laboratory					
1.	Hormones	Immunoassay with luminometric detection	Commercial procedure	Body fluids	A, B, C, D
2.	Tumor markers	Immunoassay with luminometric detection	Commercial procedure	Body fluids	A, B, C, D
3.	Proteins	Immunoassay with luminometric detection	Commercial procedure	Body fluids	A, B, C, D
4.	Vitamins	Immunoassay with luminometric detection	Commercial procedure	Body fluids	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.

"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. "