



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. 362/2025

HELLO LAB s.r.o.
with registered office Kloknerova 1245/1, Chodov, 148 00 Praha 4
Company Registration No. 10667113

for the Medical Laboratory No. 8326
HELLO LAB

Scope of accreditation:

Examinations in the field of clinical biochemistry, medical microbiology, haematology, immunohaematology and transfusion service, including shared examinations and 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.: 413/2024 of 21/08/2024, and/or any administrative acts building upon it.

The Certificate of Accreditation is valid until: 14/07/2030

Prague: 14/07/2025



Signed in the Czech original:
Marek Vyskočil on 14/07/2025

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. 362/2025 of 14/07/2025**

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

HELLO LAB s.r.o.
CAB Number 8326, HELLO LAB
Bozděchova 344/2, 150 00 Praha 5

Medical laboratory locations:

- | | | |
|----|------------------------------------------------------------|----------------------------------|
| 1. | Laboratory of Clinical Biochemistry and Haematology | Bozděchova 344/2, 150 00 Praha 5 |
| 2. | Sample collection site Bozděchova | Bozděchova 344/2, 150 00 Praha 5 |
| 3. | Sample collection site Doksy | Tovární vrch 78, 472 01 Doksy |

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.hellolab.cz/verejnost/seznam-cinnosti/>.*

1. Laboratory of Clinical Biochemistry and Haematology

Examinations:

Ordinal Number	Analyte/parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
222 – Transfusion medicine					
1.	Screening of anti-erythrocyte antibodies	Gel column agglutination	Commercial procedure	Serum, plasma	A, B
2.	Screening of anti-erythrocyte antibodies	Gel column agglutination (manual)	Commercial procedure	Serum, plasma	A, B
3.	Blood type	Gel column agglutination	Commercial procedure	Blood	A, B
4.	Blood type	Gel column agglutination (manual)	Commercial procedure	Blood	A, B
801 – Clinical Biochemistry					
1.	Urea	Absorption spectrophotometry	Commercial procedure	Serum	A, B
2.	Minerals	Potentiometry	Commercial procedure	Serum	A, B, C
3.	Enzymes	Absorption spectrophotometry	Commercial procedure	Serum	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
4.	Total protein	Absorption spectrophotometry	Commercial procedure	Serum, plasma	A, B
5.	Lipids	Absorption spectrophotometry	Commercial procedure	Serum	A, B, C
6.	Glucose	Absorption spectrophotometry	Commercial procedure	Serum, plasma	A, B
802 – Medical Microbiology					
1.	Antigens of infectious agents	Immunoassay with luminometric detection	Commercial procedure	Serum, plasma	A, B, C
2.	Antibodies to infectious agents	Immunoassay with luminometric detection	Commercial procedure	Serum, plasma	A, B, C
3.	HIV markers	Immunoassay with luminometric detection	Commercial procedure	Serum, plasma	A, B
813 - Allergology and Immunology Laboratory					
1.	Immunoglobulins	Immunoturbidimetry	Commercial procedure	Serum, plasma	A, B, C
2.	C-reactive protein (CRP)	Immunoturbidimetry	Commercial procedure	Serum	A, B
815 - Nuclear Medicine Laboratory					
1.	Hormones	Immunoassay with luminometric detection	Commercial procedure	Serum	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
818 - Haematology Laboratory					
1.	Blood count with a five-part differential leukocyte count	Flow cytometry Photometry; Impedance; 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

2. Sample collection site Bozděchova

Primary sample collection:

Ordinal Number	Sample collection technique	Identification of sample collection procedure	Collected material	Degrees of freedom ¹
1.	Venepuncture	Published procedure	Venous blood	A, B
2.	Capillary puncture	Published procedure	Capillary blood	A, B

3. Sample collection site Doksy

Primary sample collection:

Ordinal Number	Sample collection technique	Identification of sample collection procedure	Collected material	Degrees of freedom ¹
1.	Venepuncture	Published procedure	Venous blood	A, B

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Ordinal Number	Sample collection technique	Identification of sample collection procedure	Collected material	Degrees of freedom ¹
2.	Capillary puncture	Published procedure	Capillary blood	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. "