



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. **527/2025**

NL - BioLAB s. r. o.
with registered office Jankovcova 1518/2, Holešovice, 170 00 Praha 7
Company Registration No. 49827081

for the Medical Laboratory No. **8016**
Laboratoř Klatovy, Nádražní

Scope of accreditation:

Laboratory diagnostics in the field of clinical biochemistry, haematology, medical microbiology, including shared examinations and sample collection 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.: 207/2024 of 09/05/2024, and/or any administrative acts building upon it.

The Certificate of Accreditation is valid until: **09/05/2029**

Prague: 20/10/2025



Signed in the Czech original:
Marek Vyskočil on 20/10/2025

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. 527/2025 of 20/10/2025**

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

NL - BioLAB s. r. o.
CAB Number 8016, Laboratoř Klatovy, Nádražní
Nádražní 844, 339 01 Klatovy III

Medical laboratory locations:

1. **Laboratory Klatovy, Nádražní** Nádražní 844, 339 01 Klatovy
2. **Sample Collection Site Plzeň** Bedřicha Smetany 167/2, 301 00 Plzeň

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://nl-biolab.cz/nase-laboratore/nl-biolab-s-r-o-klatovy/>

1. Laboratory Klatovy, Nádražní

Examinations:

Ordinal Number	Analyte/parameter/diagnostics	Principle of examination	Identification of method procedure/equipment	Examined material	Degrees of freedom ¹
801 – Clinical Biochemistry					
1.	Non-protein nitrogenous substances	Absorption spectrophotometry	Commercial procedure	Body fluids	A, B, C, D
2.	Minerals	Potentiometry	Commercial procedure	Body fluids	A, B, C, D
3.	Glucose	Absorption spectrophotometry	Commercial procedure	Body fluids	A, B, D
4.	Proteins	Absorption spectrophotometry	Commercial procedure	Body fluids	A, B, C, D
5.	Enzymes	Absorption spectrophotometry	Commercial procedure	Body fluids	A, B, C, D
6.	Total bilirubin	Absorption spectrophotometry	Commercial procedure	Body fluids	A, B, D
7.	Lipids	Absorption spectrophotometry	Commercial procedure	Body fluids	A, B, C, D
8.	Minerals	Absorption spectrophotometry	Commercial procedure	Body fluids	A, B, C, D
9.	Glycated haemoglobin	High-Performance Liquid Chromatography	Commercial procedure	Blood	A, B

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Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of method procedure/equipment	Examined material	Degrees of freedom ¹
10.	Tumour markers	Immunoassay with luminometric detection	Commercial procedure	Body fluids	A, B, C, D
802 – Medical Microbiology					
1.	Microbiological examination of upper respiratory tract	Aerobic culture; Microscopy	Published procedure	Material of upper respiratory tract	A, B, C, D
2.	Microbiological examination of urogenital tract	Aerobic culture;	Published procedure	Urethral swab, vaginal swab	A, B, C
3.	Quantitative microbiological examination of urine	Aerobic culture;	Published procedure	Urine	A, B, C
4.	Microbiological examination of rectal swab	Aerobic culture;	Published procedure	Rectal swab, stool	A, B, C
5.	Microbiological examination of clinical material	Aerobic culture; Anaerobic cultivation; Microscopy	Published procedure	Clinical material	A, B, C, D
6.	Qualitative examination of susceptibility of microorganisms	Disk diffusion method	Published procedure	Bacterial culture	A, B, C
7.	Detection of <i>Streptococcus agalactiae</i> (screening)	Aerobic culture	Published procedure	Vaginal swab	A, B
8.	Identification of bacteria	Agglutination	Commercial procedure	Bacterial culture	A, B
9.	Identification of bacteria	Phenotyping	Published procedure	Bacterial culture	A, B
10.	Identification of microorganisms	Biochemically (automatic)	Commercial procedure	Microorganism culture	A, B, C, D

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Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of method procedure/equipment	Examined material	Degrees of freedom ¹
11.	Antigens of infectious agents	Immunoassay with luminometric detection	Commercial procedure	Body fluids	A, B, C, D
12.	HIV markers	Immunoassay with luminometric detection	Commercial procedure	Body fluids	A, B, C, D
813 - Allergology and Immunology Laboratory					
1.	C-reactive protein (CRP)	Immunoturbidimetry	Commercial procedure	Body fluids	A, B, D
815 - Nuclear Medicine Laboratory					
1.	Hormones	Immunoassay with luminometric detection	Commercial procedure	Body fluids	A, B, C, D
2.	Tumour markers	Immunoassay with luminometric detection	Commercial procedure	Body fluids	A, B, C, D
818 - Haematology Laboratory					
1.	Prothrombin test	Coagulation method with optical detection of coagulum; Calculation	Commercial procedure	Plasma	A, B
2.	Activated partial thromboplastin time	Coagulation method with optical detection of coagulum; Calculation	Commercial procedure	Plasma	A, B
3.	Blood count	Photometry; Impedance method; Flow cytometry; Calculation	Commercial procedure	Blood	A, B

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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

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2. Sample Collection Site Plzeň

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

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. "