



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. 482/2025

Unilabs Diagnostics k.s.
with registered office Evropská 2589/33b, Dejvice, 160 00 Praha 6
Company Registration No. 60470488

for the Medical Laboratory No. 8030
Laboratories Bohemia

Scope of accreditation:

Examinations in the field of clinical biochemistry, haematology, allergology and clinical immunology, medical microbiology, 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.: 529/2024 of 10/10/2024, and/or any administrative acts building upon it.

The Certificate of Accreditation is valid until: 10/10/2029

Prague: 26/09/2025



Signed in the Czech original:
Marek Vyskočil on 26/09/2025

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. 482/2025 of 26/09/2025**

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

Unilabs Diagnostics k.s.
CAB Number 8030, Laboratories Bohemia
Evropská 2589/33b, 160 00 Praha 6

Medical laboratory locations:

- | | | |
|----|---------------------------------|---|
| 1. | Workplace Hadovka | Evropská 2589/33b, 160 00 Praha 6 |
| 2. | Workplace Hradec Králové | Jeronýmova 750/1, 500 02 Hradec Králové |
| 3. | Workplace Louny | Pod Nemocnicí 2503, 440 01 Louny |
| 4. | Workplace Teplice | Lípová 738, 415 01 Teplice |

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.unilabs.cz/cs/laboratore/biochemie-a-hematologie/Aeskulab-Hadovka>

<https://www.unilabs.cz/cs/laboratore/imunologie/AeskuLab-Hadovka>

<https://www.unilabs.cz/cs/laboratore/mikrobiologie/AeskuLab-Hadovka>

<https://www.unilabs.cz/cs/laboratore/biochemie-a-hematologie/AeskuLab-Hradec-Kralove>

<https://www.unilabs.cz/cs/laboratore/biochemie-a-hematologie/AeskuLab-Louny>

<https://www.unilabs.cz/cs/laboratore/biochemie-a-hematologie/Aeskulab-Teplice>

1. Workplace Hadovka

Examinations:

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
801 – Clinical Biochemistry					
1.	Proteins	Absorption spectrophotometry	Commercial procedure	Serum	A, B, C
2.	Minerals	Potentiometry	Commercial procedure	Serum	A, B, C
3.	Minerals	Absorption spectrophotometry	Commercial procedure	Body fluids	A, B, C, D
4.	Non-protein nitrogenous compounds	Absorption spectrophotometry	Commercial procedure	Body fluids	A, B, C, D
5.	Lipids	Absorption spectrophotometry	Commercial procedure	Body fluids	A, B, C, D
6.	Enzymes	Absorption spectrophotometry	Commercial procedure	Body fluids	A, B, C, D
7.	Pigments	Absorption spectrophotometry	Commercial procedure	Body fluids	A, B, C, D

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Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
8.	Saccharides	Absorption spectrophotometry	Commercial procedure	Body fluids	A, B, C, D
9.	Tumor markers	Immunoassay with luminometric detection	Commercial procedure	Body fluids	A, B, C, D
802 – Medical Microbiology					
1.	HIV markers	Immunoassay with luminometric detection	Commercial procedure	Body fluids	A, B, C, D
2.	Antibodies against infectious agents	Immunoassay with luminometric detection	Commercial procedure	Body fluids	A, B, C, D
3.	Antigens of infectious agents	Immunoassay with luminometric detection	Commercial procedure	Body fluids	A, B, C, D
4.	Antibodies against infectious agents	Immunoassay with luminometric detection	Commercial procedure	Body fluids	A, B, C, D
5.	Microbiological examination of upper respiratory tract	Aerobic culture	Commercial procedure	Material of upper respiratory tract	A, B, C, D
6.	Microbiological examination of the lower respiratory tract	Aerobic culture; Microscopy	Commercial procedure	Material of lower respiratory tract	A, B, C, D
7.	Quantitative microbiological examination of urine	Aerobic culture	Commercial procedure	Urine	A, B, C
8.	Microbiological examination of rectal swab	Aerobic culture	Commercial procedure	Rectal swab, stool	A, B, C
9.	Microbiological examination of clinical material	Aerobic culture; Anaerobic culture	Commercial procedure	Clinical material	A, B, C, D

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Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
10.	Microbiological examination of urogenital tract	Aerobic culture; Anaerobic culture	Commercial procedure	Genitourinary system material	A, B, C, D
11.	Identification of microorganisms	Mass spectrometry	Commercial procedure	Microorganism culture	A, B, C, D
12.	Identification of bacteria	Agglutination	Commercial procedure	Microorganism culture	A, B, C, D
13.	Identification of microorganisms	Phenotyping	Commercial procedure	Microorganism culture	A, B, C, D
14.	Antibiotic susceptibility testing	Disk diffusion test	Commercial procedure	Microorganism culture	A, B, C, D
15.	Quantitative examination of microorganism sensitivity	E-test	Commercial procedure	Microorganism culture	A, B, C, D
16.	Microbiological examination of blood and primarily sterile body fluids	Aerobic culture; Anaerobic culture (automated)	Commercial procedure	Liquid clinical material	A, B, C, D
17.	Screening for clinically significant resistance	Aerobic culture	Commercial procedure	Microorganism culture	A, B, C, D
813 - Allergology and Immunology Laboratory					
1.	Specific proteins	Immunoturbidimetry	Commercial procedure	Body fluids	A, B, C, D
2.	Rheumatoid factor (RF)	Immunoturbidimetry	Commercial procedure	Body fluids	A, B, D
3.	Immunoglobulins	Immunoturbidimetry	Commercial procedure	Body fluids	A, B, C, D
4.	Immunoglobulin E	Immunoassay with luminometric detection	Commercial procedure	Body fluids	A, B, D

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Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
5.	Immunophenotyping of cell populations	Flow cytometry	Commercial procedure	Body fluids	A, B, C, D
6.	Autoantibodies	Indirect immunofluorescence	Commercial procedure	Body fluids	A, B, C, D
7.	Specific IgE	Immunoassay with luminometric detection	Commercial procedure	Body fluids	A, B, D
8.	Autoantibodies	Immunoassay with photometric detection (automatická)	Commercial procedure	Body fluids	A, B, C, D
815 - Nuclear Medicine Laboratory					
1.	Hormones	Immunoassay with luminometric detection	Commercial procedure	Body fluids	A, B, C, D
2.	Autoantibodies	Immunoassay with luminometric detection	Commercial procedure	Body fluids	A, B, C, D
818 - Haematology Laboratory					
1.	Blood count with a five-part differential leukocyte count	Flow cytometry; Impedance method; Photometry; Calculations	Commercial procedure	Blood	A, B, C
2.	Prothrombin test	Coagulation method with optical detection of coagulum; Calculation	Commercial procedure	Plasma	A, B
3.	D-dimers	Immunoassay with turbidimetric detection	Commercial procedure	Plasma	A, B

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Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom¹
4.	Activated partial thromboplastin time	Coagulation method with optical detection of coagulum; Calculation	Commercial procedure	Plasma	A, B
5.	Fibrinogen	Coagulation method with optical detection of coagulum	Commercial procedure	Plasma	A, B

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2. Workplace Hradec Králové

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	Body fluids	A, B, C, D
2.	Lipids	Absorption spectrophotometry	Commercial procedure	Body fluids	A, B, C, D
3.	Enzymes	Absorption spectrophotometry	Commercial procedure	Body fluids	A, B, C, D
4.	Pigments	Absorption spectrophotometry	Commercial procedure	Body fluids	A, B, C, D
813 - Allergology and Immunology Laboratory					
1.	Specific proteins	Immunoturbidimetry	Commercial procedure	Body fluids	A, B, C, D

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3. Workplace Louny

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 (automated)	Commercial procedure	Blood	A, B
2.	Screening of anti-erythrocyte antibodies	Gel column agglutination	Commercial procedure	Plasma, serum	A, B
801 – Clinical Biochemistry					
1.	Proteins	Absorption spectrophotometry	Commercial procedure	Serum	A, B, C
2.	Enzymes	Absorption spectrophotometry	Commercial procedure	Body fluids	A, B, C, D
3.	Pigments	Absorption spectrophotometry	Commercial procedure	Body fluids	A, B, C, D
4.	Minerals	Potentiometry	Commercial procedure	Serum, urine	A, B, C
5.	Saccharides	Absorption spectrophotometry	Commercial procedure	Body fluids	A, B, C, D
6.	Glycated haemoglobin	High-Performance Liquid Chromatography	Commercial procedure	Body fluids	A, B, D
7.	Lipids	Absorption spectrophotometry	Commercial procedure	Body fluids	A, B, C, D
8.	Non-protein nitrogenous compounds	Absorption spectrophotometry	Commercial procedure	Body fluids	A, B, C, D
9.	Minerals	Absorption spectrophotometry	Commercial procedure	Body fluids	A, B, C, D

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Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
10.	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	Body fluids	A, B, C, D
815 - Nuclear Medicine Laboratory					
1.	Hormones	Immunoassay with luminometric detection	Commercial procedure	Body fluids	A, B, C, D
818 - Haematology Laboratory					
1.	Antithrombin	Chromogenic method	Commercial procedure	Plasma	A, B
2.	Prothrombin test	Coagulation method with optical detection of coagulum; Calculation	Commercial procedure	Plasma	A, B
3.	Activated partial thromboplastin time	Coagulation method with optical detection of coagulum; Calculations	Commercial procedure	Plasma	A, B
4.	D-dimers	Immunoassay with turbidimetric detection	Commercial procedure	Plasma	A, B
5.	Fibrinogen	Coagulation method with optical detection of coagulum; Calculation	Commercial procedure	Plasma	A, B
6.	Blood count	Flow cytometry; Impedance method; Photometry; Calculations	Commercial procedure	Blood	A, B, C

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4. Workplace Teplice

Examinations:

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
801 – Clinical Biochemistry					
1.	Enzymes	Absorption spectrophotometry	Commercial procedure	Body fluids	A, B, C, D
2.	Pigments	Absorption spectrophotometry	Commercial procedure	Body fluids	A, B, C, D
3.	Lipids	Absorption spectrophotometry	Commercial procedure	Body fluids	A, B, C, D
4.	Non-protein nitrogenous compounds	Absorption spectrophotometry	Commercial procedure	Body fluids	A, B, C, D
5.	Minerals	Potentiometry	Commercial procedure	Body fluids	A, B, C
6.	Saccharides	Absorption spectrophotometry	Commercial procedure	Body fluids	A, B, C, D
7.	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	Body fluids	A, B, C, D
815 - Nuclear Medicine Laboratory					
1.	Hormones	Immunoassay with luminometric detection	Commercial procedure	Body fluids	A, B, C, D
818 - Haematology Laboratory					

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Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
1.	Prothrombin test	Coagulation method with optical detection of coagulum; Calculation	Commercial procedure	Plasma	A, B
2.	D-dimers	Immunoassay with turbidimetric detection	Commercial procedure	Plasma	A, B
3.	Blood count	Flow cytometry; Impedance method; Photometry; Calculations	Commercial procedure	Blood	A, B, C

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. "