



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. 42/2026

Krajská nemocnice Liberec, a.s.
with registered office Husova 1430/34, Liberec I - Staré Město, 460 01 Liberec
Company Registration No. 27283933

for the Medical Laboratory No. **8237**
Centrum laboratorní medicíny (CLM)

Scope of accreditation:

Laboratory diagnostics in the field of immunohaematology and transfusion service, haematology, clinical biochemistry, medical microbiology, allergology and clinical immunology, 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.: 652/2025 of 15/12/2025, and/or any administrative acts building upon it.

The Certificate of Accreditation is valid until: **15/12/2030**

Prague: 26/01/2026



Signed in the Czech original:
Milena Lochmanová on 26/01/2026

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. 42/2025 of 26/01/2026**

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

Krajská nemocnice Liberec, a.s.
CAB Number 8237, Centrum laboratorní medicíny (CLM)
Husova 1430/34, Liberec I - Staré Město, 460 01 Liberec

Medical laboratory locations:

- | | | |
|----|---|---|
| 1. | OKH - Clinical Haematology Department | Baarova 526/15, Liberec I – Staré Město, 460 01 Liberec |
| 2. | TO - Transfusion Department | Baarova 526/15, Liberec I – Staré Město, 460 01 Liberec |
| 3. | OKB - Department of Clinical Biochemistry | Husova 357/10, Liberec I – Staré Město, 460 01 Liberec |
| 4. | OKMI - Clinical Microbiology and Immunology Department | Husova 357/10, Liberec I – Staré Město, 460 01 Liberec |
| 5. | Laboratory of Clinical Biochemistry and Haematology | Nemocnice Frýdlant, V Úvoze 860, 464 01 Frýdlant |
| 6. | Laboratory of Clinical Biochemistry and Haematology | Nemocnice Turnov, 28. října 1000, 51101 Turnov |

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.nemlib.cz/clm/>

1. OKH - Clinical Haematology Department

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	Flow cytometry; Impedance method; Photometry; Calculations	Commercial procedure	Blood	A, B, C
2.	Blood count with a five-part differential leukocyte count	Flow cytometry; Impedance method; Photometry; Calculations	Commercial procedure	Blood	A, B
3.	Peripheral blood smear test	Microscopy	Published procedure	Blood	A, B
4.	Peripheral blood smear test	Digital microscopy	Published procedure	Blood	A, B

**The Appendix is an integral part of
Certificate of Accreditation No. 42/2025 of 26/01/2026**

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

Krajská nemocnice Liberec, a.s.
CAB Number 8237, Centrum laboratorní medicíny (CLM)
Husova 1430/34, Liberec I - Staré Město, 460 01 Liberec

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/ equipment	Examined material	Degrees of freedom ¹
5.	Prothrombin test	Coagulation method with optical detection of coagulum; Calculations	Commercial procedure	Plasma	A, B
6.	Activated partial thromboplastin time	Coagulation method with optical detection of coagulum; Calculations	Commercial procedure	Plasma	A, B
7.	Fibrinogen	Coagulation method with optical detection of coagulum	Commercial procedure	Plasma	A, B
8.	Antithrombin	Chromogenic method	Commercial procedure	Plasma	A, B
9.	D-dimers	Immunoassay with turbidimetric detection	Commercial procedure	Plasma	A, B

**The Appendix is an integral part of
Certificate of Accreditation No. 42/2025 of 26/01/2026**

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

Krajská nemocnice Liberec, a.s.
CAB Number 8237, Centrum laboratorní medicíny (CLM)
Husova 1430/34, Liberec I - Staré Město, 460 01 Liberec

2. TO - Transfusion Department

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	Agglutination in test tubes	Commercial procedure	Blood	A, B
2.	Blood type	Gel column agglutination	Commercial procedure	Blood	A, B, C
3.	Screening of anti-erythrocyte antibodies	Gel column agglutination	Commercial procedure	Plasma, serum	A, B
4.	Examination of compatibility	Gel column agglutination	Commercial procedure	Plasma, serum	A, B

**The Appendix is an integral part of
Certificate of Accreditation No. 42/2025 of 26/01/2026**

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

Krajská nemocnice Liberec, a.s.
CAB Number 8237, Centrum laboratorní medicíny (CLM)
Husova 1430/34, Liberec I - Staré Město, 460 01 Liberec

3. OKB - Department of Clinical Biochemistry

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	Body fluids	A, B, C, D
2.	Non-protein nitrogenous substances	Absorption spectrophotometry	Commercial procedure	Body fluids	A, B, C, D
3.	Saccharides	Absorption spectrophotometry	Commercial procedure	Body fluids	A, B, C, D
4.	Pigments	Absorption spectrophotometry	Commercial procedure	Serum, plasma	A, B, C
5.	Enzymes	Absorption spectrophotometry	Commercial procedure	Serum, plasma	A, B, C
6.	Lipids	Absorption spectrophotometry	Commercial procedure	Serum, plasma	A, B, C
7.	Glycated haemoglobin	High-Performance Liquid Chromatography	Commercial procedure	Blood	A, B
8.	Cardiac markers	Immunoassay with luminometric detection	Commercial procedure	Serum, plasma	A, B, C
9.	Acid-base balance	Potentiometry; Amperometry	Commercial procedure	Blood	A, B, C
10.	Tumour markers	Immunoassay with luminometric detection	Commercial procedure	Serum, plasma	A, B, C
11.	Markers for the calculation of the risk of congenital developmental defects	Immunoassay with luminometric detection	Commercial procedure	Body fluids	A, B, C, D
12.	Hormones	Immunoassay with luminometric detection	Commercial procedure	Serum, plasma	A, B, C
13.	Immunoglobulins	Immunoassay with luminometric detection	Commercial procedure	Body fluids	A, B, C, D

**The Appendix is an integral part of
Certificate of Accreditation No. 42/2025 of 26/01/2026**

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

Krajská nemocnice Liberec, a.s.
CAB Number 8237, Centrum laboratorní medicíny (CLM)
Husova 1430/34, Liberec I - Staré Město, 460 01 Liberec

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
813 - Allergology and Immunology Laboratory					
1.	Specific proteins	Immunoturbidimetry	Commercial procedure	Body fluids	A, B, C, D
2.	Immunoglobulins	Immunoturbidimetry	Commercial procedure	Body fluids	A, B, C, D
815 - Nuclear Medicine Laboratory					
1.	Tumour markers	Immunoassay with luminometric detection	Commercial procedure	Serum, plasma	A, B, C

Primary sample collection:

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

**The Appendix is an integral part of
Certificate of Accreditation No. 42/2025 of 26/01/2026**

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

Krajská nemocnice Liberec, a.s.
CAB Number 8237, Centrum laboratorní medicíny (CLM)
Husova 1430/34, Liberec I - Staré Město, 460 01 Liberec

4. OKMI - Clinical Microbiology and Immunology Department

Examinations:

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
802 – Medical Microbiology					
1.	Quantitative microbiological examination of urine	Aerobic culture	Published procedure	Urine	A, B
2.	Microbiological examination of urine	Aerobic culture; Microscopy	Published procedure	Urine	A, B
3.	Microbiological examination of blood and primarily sterile body fluids	Aerobic culture; Anaerobic culture (automated)	Published procedure; Commercial procedure	Clinical material	A, B, C, D
4.	Microbiological examination of upper respiratory tract	Aerobic culture	Published procedure	Material of upper respiratory tract	A, B, C, D
5.	Microbiological examination of lower respiratory tract	Aerobic culture; Anaerobic culture; Microscopy	Published procedure	Material of lower respiratory tract	A, B, C, D
6.	Microbiological examination of lower respiratory tract	Aerobic culture; Microscopy	Published procedure	Material of lower respiratory tract	A, B, C, D
7.	Microbiological examination of lower respiratory tract	Aerobic culture	Published procedure	Material of lower respiratory tract	A, B, C, D
8.	Microbiological examination for mycobacteria	Aerobic culture; Microscopy; Fluorescence microscopy	Published procedure; Commercial procedure	Clinical material	A, B, D
9.	Mycobacteria test	Aerobic culture	Published procedure	Clinical material	A, B, D

**The Appendix is an integral part of
Certificate of Accreditation No. 42/2025 of 26/01/2026**

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

Krajská nemocnice Liberec, a.s.
CAB Number 8237, Centrum laboratorní medicíny (CLM)
Husova 1430/34, Liberec I - Staré Město, 460 01 Liberec

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
10.	Identification of mycobacteria	Phenotyping	Published procedure	Mycobacterial strain	A, B, D
11.	Microbiological examination of and rectal swab	Aerobic culture; Anaerobic culture	Published procedure	Stool, rectal swab	A, B
12.	Microbiological examination of clinical material	Aerobic culture	Published procedure	Clinical material	A, B, C, D
13.	Microbiological examination of clinical material	Anaerobic culture; Aerobic culture; Microscopy	Published procedure	Clinical material	A, B, C, D
14.	Microbiological examination of clinical material	Anaerobic culture; Aerobic culture	Published procedure	Clinical material	A, B, C, D
15.	Mycological examination of clinical material	Aerobic culture; Microscopy	Published procedure	Clinical material	A, B, C, D
16.	Microbiological examination for mycobacteria	Aerobic culture (automated)	Published procedure; Commercial procedure	Clinical material	A, B, C, D
17.	Microbiological examination of urogenital tract	Aerobic culture; Microscopy	Published procedure	Genitourinary system material	A, B, D
18.	Detection of <i>Neisseria gonorrhoeae</i>	Aerobic culture; Microscopy	Published procedure	Clinical material	A, B, D
19.	Identification of microorganism	Phenotyping	Published procedure	Microorganism culture	A, B
20.	Identification of microorganism	Agglutination	Published procedure	Microorganism culture	A, B
21.	Identification of microorganism	Mass spectrometry	Commercial procedure	Microorganism culture	A, B, D
22.	Antibiotic susceptibility testing	Disk diffusion test	Published procedure	Microorganism culture	A, B, D

**The Appendix is an integral part of
Certificate of Accreditation No. 42/2025 of 26/01/2026**

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

Krajská nemocnice Liberec, a.s.
CAB Number 8237, Centrum laboratorní medicíny (CLM)
Husova 1430/34, Liberec I - Staré Město, 460 01 Liberec

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
23.	Quantitative examination of microorganism sensitivity	E-test	Published procedure	Microorganism culture	A, B, D
24.	Microbiological examination of cerebrospinal fluid	Aerobic culture; Microscopy	Published procedure	Cerebrospinal fluid	A, B
25.	Microbiological examination of foreign bodies	Aerobic culture; Anaerobic culture	Published procedure	Foreign bodies	A, B, C, D
26.	Microbiological examination of foreign bodies	Aerobic culture; Anaerobic culture; Microscopy	Published procedure	Foreign bodies	A, B, C, D
27.	Antibodies against leptospire	Microscopic agglutination test	Published procedure	Serum, plasma	A, B, C
28.	Parasitological examination of stool	Microscopy	Published procedure	Stool	A, B, C
29.	Enterobiosis examination	Microscopy	Published procedure	Perianal smear or imprint	A, B
30.	Morphological identification of the parasite	Macroscopic identification	Published procedure	Suspicious entity	A, B, D
31.	Antibodies against infectious agent	Immunoassay with photometric detection	Commercial procedure	Serum, plasma	A, B, C
32.	Antibodies against infectious agent	Indirect immunofluorescence	Commercial procedure; Published procedure	Serum, plasma	A, B, C
33.	Antibodies against infectious agent	Immunoassay with luminometric detection	Commercial procedure	Serum, plasma	A, B, C
34.	Antigens of infectious agents	Immunoassay with luminometric detection	Commercial procedure	Body fluids	A, B, C, D

**The Appendix is an integral part of
Certificate of Accreditation No. 42/2025 of 26/01/2026**

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

Krajská nemocnice Liberec, a.s.
CAB Number 8237, Centrum laboratorní medicíny (CLM)
Husova 1430/34, Liberec I - Staré Město, 460 01 Liberec

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
35.	Non-specific antibodies against <i>Treponema pallidum</i>	Agglutination	Published procedure	Serum, plasma	A, B
813 - Allergology and Immunology Laboratory					
1.	Immunoglobulins	Immunoturbidimetry	Commercial procedure	Serum, plasma	A, B, C
2.	Specific proteins	Immunoturbidimetry	Commercial procedure	Serum, plasma	A, B, C
3.	Autoantibodies	Indirect immunofluorescence	Commercial procedure; Published procedure	Serum, plasma	A, B, C
4.	Immunophenotyping of leukocytes	Flow cytometry	Commercial procedure	Blood	A, B, C
5.	Specific IgE	Immunoassay with fluorimetric detection	Commercial procedure	Serum, plasma	A, B, C
6.	Antibodies against <i>Saccharomyces cerevisiae</i>	Immunoassay with photometric detection	Commercial procedure	Serum, plasma	A, B

Primary sample collection:

Ordinal Number	Sample collection technique	Identification of sample collection procedure	Collected material	Degrees of freedom ¹
1.	Smear	Published procedure	Smears of skin, soft tissue, ear, eye, smears (of lesions, pus, etc.), smears of skin pustulae and blisters, smear of nail plate	A, B
2.	Swab	Published procedure	Nasal, nasopharyngeal, throat, laryngeal, eye or ear swab, vaginal, cervical, urethral, rectal, vaginorectal, urogenital swab	A, B
3.	Collection	Published procedure	Nails, skin flakes, hair, samples of skin flakes, hair, samples from fingernails, toenails	A, B
4.	Scraping	Published procedure	Skin scraping, nail scraping	A, B
5.	Capillary puncture	Published procedure	Capillary blood	A, B

**The Appendix is an integral part of
Certificate of Accreditation No. 42/2025 of 26/01/2026**

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

Krajská nemocnice Liberec, a.s.
CAB Number 8237, Centrum laboratorní medicíny (CLM)
Husova 1430/34, Liberec I - Staré Město, 460 01 Liberec

5. 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
801 – Clinical Biochemistry					
1.	Minerals	Potentiometry	Commercial procedure	Body fluid	A, B, C, D
2.	Non-protein nitrogenous substances	Absorption spectrophotometry	Commercial procedure	Body fluid	A, B, C, D
3.	Saccharides	Absorption spectrophotometry	Commercial procedure	Body fluid	A, B, C, D
4.	Pigments	Absorption spectrophotometry	Commercial procedure	Serum, plasma	A, B, C
5.	Enzymes	Absorption spectrophotometry	Commercial procedure	Serum, plasma	A, B, C
6.	Lipids	Absorption spectrophotometry	Commercial procedure	Serum, plasma	A, B, C
7.	Glycated haemoglobin	High-Performance Liquid Chromatography	Commercial procedure	Blood	A, B
8.	Hormones	Immunoassay with luminometric detection	Commercial procedure	Serum, plasma	A, B, C

**The Appendix is an integral part of
Certificate of Accreditation No. 42/2025 of 26/01/2026**

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

Krajská nemocnice Liberec, a.s.
CAB Number 8237, Centrum laboratorní medicíny (CLM)
Husova 1430/34, Liberec I - Staré Město, 460 01 Liberec

6. 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.	Blood type	Gel column agglutination (manual)	Commercial procedure	Blood	A, B
2.	Examination of compatibility	Gel column agglutination (manual)	Commercial procedure	Serum, plasma	A, B
3.	Screening of anti-erythrocyte antibodies	Gel column agglutination (manual)	Commercial procedure	Serum, plasma	A, B
801 – Clinical Biochemistry					
1.	Glucose	Absorption spectrophotometry	Commercial procedure	Body fluids	A, B, D
2.	Minerals	Potentiometry	Commercial procedure	Body fluids	A, B, C, D
3.	Total Calcium	Absorption spectrophotometry	Commercial procedure	Body fluids	A, B, D
4.	Non-protein nitrogenous substances	Absorption spectrophotometry	Commercial procedure	Body fluids	A, B, C, D
5.	Total bilirubin	Absorption spectrophotometry	Commercial procedure	Body fluids	A, B, D
6.	Enzymes	Absorption spectrophotometry	Commercial procedure	Body fluids	A, B, C, D
7.	Lipids	Absorption spectrophotometry	Commercial procedure	Body fluids	A, B, C, D
8.	Total protein	Absorption spectrophotometry	Commercial procedure	Body fluids	A, B, D

**The Appendix is an integral part of
Certificate of Accreditation No. 42/2025 of 26/01/2026**

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

Krajská nemocnice Liberec, a.s.
CAB Number 8237, Centrum laboratorní medicíny (CLM)
Husova 1430/34, Liberec I - Staré Město, 460 01 Liberec

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
813 - Allergy and Immunology Laboratory					
1.	C-reactive protein (CRP)	Immunoturbidimetry	Commercial procedure	Serum, plasma	A, B
818 - Haematology Laboratory					
1.	Blood 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

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

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. "