**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. **397/2026**

**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. **8182**
Centrální klinické laboratoře (CKL)

Scope of accreditation:

Examinations in the fields of clinical biochemistry, hematology, immunohematology and transfusion medicine, and medical microbiology, including shared examinations and blood sampling 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.: 16/2026 of 09/01/2026, and/or any administrative acts building upon it.

The Certificate of Accreditation is valid until: **06/05/2030**

Prague: 19/08/2026

Český institut pro akreditaci, o.p.s.
«CAI»

Signed in the Czech original:
Vojtěch Jurga on 19/08/2026

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. 397/2026 of 19. 8. 2026**

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

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CAB Number 8182, Centrální klinické laboratoře (CKL)
Purkyňova 1849, 470 01 Česká Lípa

*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/oddeleni-manazera-kvality/akreditace-oceneni-certifikaty/*

## 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 (manual) | Commercial procedure | Serum, plasma | A, B |
| 2. | Blood type | Gel column agglutination (manual) | Commercial procedure | Umbilical cord blood | A, B |
| 3. | Blood type | Agglutination in test tubes | Commercial procedure | Blood | A, B |
| 4. | Examination of compatibility | 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. | Enzymes | 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 | Absorption spectrophotometry | Commercial procedure | Body fluids | A, B, C, D |
| 6. | Minerals | Potentiometry | 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] |
|---|---|---|---|---|---|
| 7. | Pigments | Absorption spectrophotometry | Commercial procedure | Body fluids | A, B, C, D |
| 8. | Proteins | Absorption spectrophotometry | Commercial procedure | Body fluids | A, B, C, D |
| 9. | Acid-base balance | Potentiometry;<br>Amperometry | Commercial procedure | Blood | A, B |
| 10. | Glycated haemoglobin | High-Performance Liquid Chromatography | Commercial procedure | Blood | A, B |
| 11. | Cardiac markers | Immunoassay with luminometric detection | Commercial procedure | Body fluids | A, B, C, D |
| 12. | Tumor markers | Immunoassay with luminometric detection | Commercial procedure | Body fluids | A, B, C, D |
| 13. | Hormones | Immunoassay with luminometric detection | Commercial procedure | Body fluids | A, B, C, D |
| 14. | Ferritin | Immunoassay with luminometric detection | Commercial procedure | Body fluids | A, B, D |
| **802 – Medical Microbiology** | | | | | |
| 1. | Antibiotic susceptibility testing | Disk diffusion test | Commercial procedure;<br>Published procedure | Bacterial culture | A, B |
| 2. | Identification of the microorganism | Mass spectrometry | Commercial procedure | Bacterial culture, yeast culture | A, B |
| 3. | Identification of bacteria | Agglutination | Commercial procedure | Bacterial culture | A, B, C |
| 4. | Identification of the microorganism | Phenotyping | Commercial procedure;<br>Published procedure | Microorganism culture | 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] |
|---|---|---|---|---|---|
| 5. | Microbiological examination of upper respiratory tract | Aerobic culture | Published procedure | Material of upper respiratory tract | A, B, D |
| 6. | Quantitative microbiological examination of urine | Aerobic culture;<br>Nephelometry | Commercial procedure;<br>Published procedure | Urine | A, B |
| 7. | Microbiological examination of rectal swab | Aerobic culture | Published procedure | Rectal swab | A, B |
| 8. | Microbiological examination of primarily sterile body fluids | Microscopy;<br>Aerobic culture;<br>Anaerobic culture | Commercial procedure;<br>Published procedure | Liquid clinical material | A, B, D |
| 9. | Microbiological examination of primarily sterile body fluids | Aerobic culture;<br>Anaerobic culture<br>(automated) | Commercial procedure;<br>Published procedure | Liquid clinical material | A, B, D |
| 10. | Microbiological examination of primarily sterile body fluids | Latex agglutination | Commercial procedure | Cerebrospinal fluid | A, B |
| 11. | Microbiological examination of clinical material | Aerobic culture;<br>Anaerobic culture | Published procedure | Clinical material | A, B, D |
| 12. | Microbiological examination of clinical material | Microscopy;<br>Aerobic culture;<br>Anaerobic culture | Published procedure | Clinical material | A, B, D |
| 13. | Microbiological examination of foreign bodies | Aerobic culture | Published procedure | Foreign bodies | A, B, D |
| 14. | Microbiological examination of the lower respiratory tract | Microscopy;<br>Aerobic culture | Published procedure | Material of lower respiratory tract | 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] |
|---|---|---|---|---|---|
| 15. | Microbiological examination of urogenital tract | Microscopy;<br>Aerobic culture;<br>Anaerobic culture | Published procedure | Genitourinary system material | A, B, D |
| 16. | Antigens of infectious agents | Immunoassay with luminometric detection | Commercial procedure | Serum, plasma | A, B, C |
| 17. | Antibodies against infectious agents | Immunoassay with luminometric detection | Commercial procedure | Serum, plasma | A, B, C |
| 18. | HIV markers | Immunoassay with luminometric detection | Commercial procedure | Serum, plasma | A, B |
| **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 |
| **818 - Haematology Laboratory** | | | | | |
| 1. | Blood count | Flow cytometry;<br>Impedance method;<br>Photometry;<br>Calculations | Commercial procedure | Blood | A, B, C |
| 2. | Peripheral blood smear test | Microscopy | Published procedure | Blood | A, B |
| 3. | Peripheral blood smear test | Digital microscopy | Published procedure | Blood | A, B |

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| Ordinal number | Analyte/ parameter/diagnostics | Principle of examination | Identification of procedure/equipment | Examined material | Degrees of freedom[1] |
|---|---|---|---|---|---|
| 4. | Prothrombin test | Coagulation method with optical detection of coagulum;<br>Calculation | Commercial procedure | Plasma | A, B |
| 5. | Activated partial thromboplastin time | Coagulation method with optical detection of coagulum | Commercial procedure | Plasma | A, B |
| 6. | Fibrinogen | Coagulation method with optical detection of coagulum | Commercial procedure | Plasma | A, B |
| 7. | Antithrombin | Chromogenic method | Commercial procedure | Plasma | A, B |

## Primary sample collection:

| Ordinal Number | Sample collection technique | Identification of sample collection procedure | Collected material | Degrees od 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. "*