



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. 702/2025

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. 8306
PATOS Center - laboratories

Scope of accreditation:

Laboratory examinations in the fields of histopathology, cytopathology, toxicology and molecular genetics 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.: 89/2025 of 28/02/2025, and/or any administrative acts building upon it.

The Certificate of Accreditation is valid until: **30/12/2030**

Prague: 30/12/2025



Signed in the Czech original:
Marek Vyskočil on 30/12/2025

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. 702/2025 of 30/12/2025**

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

Krajská nemocnice Liberec, a.s.
CAB Number 8306, PATOS Center – Laboratories
Husova 1430/34, Liberec I-Staré Město, 460 01 Liberec

Medical laboratory locations:

- | | | |
|----|--|----------------------------------|
| 1. | PAT – Department of Pathology | Husova 1430/34, 460 01 Liberec 1 |
| 2. | PAT – Department of Pathology | Vídeňská 1958/9, 140 00 Praha 4 |
| 3. | TOXI – Department of Forensic Medicine
and Toxicology | Husova 1430/34, 460 01 Liberec 1 |
| 4. | OGMD – Department of Genetics and Molecular
Diagnostics | Husova 1430/34, 460 01 Liberec 1 |

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/centrum-patos/>

1. PAT – Department of Pathology

Examinations:

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
823 - Pathology Laboratory					
1.	Histological examination and diagnostics	Microscopy	Published procedure; In-house procedure	Tissues	A, B
2.	Cytological examination and diagnostics	Microscopy	Published procedure; In-house procedure	Cells	A, B
3.	Immunohistochemical and immunocytochemical examination of antigens	Microscopy	Commercial procedure; Published procedure; In-house procedure	Tissues, cells	A, B, C
4.	Intraoperative histological and cytological examination and diagnostics	Microscopy	Published procedure; In-house procedure	Tissues, cells	A, B
5.	Examination of histological and cytological samples	In situ hybridization	Commercial procedure; Published procedure; In-house procedure	Tissues, cells	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
6.	Examination of somatic genome variants	Real-Time PCR	Commercial procedure	Biological material containing human tumor DNA/RNA	A, B, C, D
7.	Examination of somatic genome variants	PCR with fragment analysis	Commercial procedure	Biological material containing human tumor DNA/RNA	A, B, C, D
8.	Examination of somatic genome variants	NGS-MPS	Commercial procedure	Biological material containing human tumor DNA/RNA	A, B, C, D

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2. PAT – Department of Pathology

Examinations:

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
823 - Pathology Laboratory					
1.	Examination of somatic genome variants	Real-Time PCR	Commercial procedure	Biological material containing human tumor DNA/RNA	A, B, C, D

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3. TOXI – Department of Forensic Medicine and Toxicology

Examinations:

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
814 - Toxicological Laboratory					
1.	Ethyl alcohol	GC-FID	In-house procedure	Blood, serum, urine	A, B
2.	Ethyl alcohol	Enzymatic method with alcohol dehydrogenase	Commercial procedure	Blood, serum, urine	A, B
3.	Neuroleptics determination	LC-MS	In-house procedure	Serum	A, B, C

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4. OGMD – Department of Genetics and Molecular Diagnostics

Examinations:

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
802 – Medical Microbiology					
1.	Detection of nucleic acids of infectious agents	Real-Time PCR	Commercial procedure	Clinical material	A, B, C, D
816 – Medical Genetics Laboratory					
1.	Examination of germline genome variants	Real-Time PCR	Commercial procedure	Biological material containing human nucleic acid	A, B, C, D
2.	Examination of germline genome variants	NGS-MPS	Commercial procedure	Biological material containing human nucleic acid	A, B, C, D
3.	Examination of chromosome aneuploidy	PCR with fragment analysis	Commercial procedure	Blood, tissue	A, B, C
4.	Examination of somatic genome variants	MLPA	Commercial procedure	Biological material containing human nucleic acid	A, B, C, D
5.	Examination of somatic genome variants	Direct sequencing (acc. to Sanger)	Commercial procedure	Biological material containing human nucleic acid	A, B, C, D

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.

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NGS-MPS	Massively parallel sequencing
GC-FID	Gas Chromatography with Flame Ionization Detection
Real-Time PCR	Real-Time Polymerase Chain Reaction
MLPA	Multiplex ligation-dependent probe amplification
LC-MS	Liquid chromatography with mass spectrometry detection

"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. "