The Appendix is an integral part of Certificate of Accreditation No 164/2024 of 10/04/2024

Accredited entity according to ČSN EN ISO 15189 ed. 2:2013:

Krajská nemocnice Liberec, a.s.

CAB Number 8306, PATOS Center – Laboratories Husova 1430/34, Liberec I-Staré Město, 460 01 Liberec

Medical laboratory locations:

PAT – Department of Pathology
 TOXI – Department of Forensic Medicine and Toxicology
 Husova 1430/34, 460 01 Liberec 1
 Husova 1430/34, 460 01 Liberec 1

3. **OGMD – Department of Genetics and Molecular** Husova 1430/34, 460 01 Liberec 1 **Diagnostics**

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 <u>Centrum PATOS – Krajská</u> nemocnice Liberec (nemlib.cz)

1. **PAT – Department of Pathology**

Examinations:

Ordinal Number	Analyt / Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/ equipment	Examined material	Degrees of freedom ¹		
	823 - Pathology Laboratory						
1.	Histological examination of tissue 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 and cells	A, B, C		
4.	Peroperational histological and cytological examination and diagnostics	Microscopy	Published procedure; In-house procedure	Tissues and cells	A, B		
5.	Examination of histological and cytological samples	In-situ hybridization	Commercial procedure; Published procedure; In-house procedure	Tissues and cells	A, B, C		

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Ordinal Number	Analyt / 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	Real-Time PCR	Commercial procedure	Biological material containing human tumor DNA/RNA	A, B, C, D
8.	Examination of somatic genome variants	PCR with reverse hybridization	Commercial procedure	Biological material containing human tumor DNA/RNA	A, B, C, D
9.	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. 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.	Screening nox	Immunochemical test	Commercial procedure	Urine	A, B, C	
4.	Detection of volatile substances	GC-FID	In-house procedure	Blood, serum, urine	A, B	

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3. OGMD – Department of Genetics and Molecular Diagnostics

Examinations:

Ordin al Numb er	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 DNA/RNA	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

If no degree of freedom is specified, the laboratory cannot apply a flexible approach to the scope of accreditation for this examination.

NGS-MPS Massively parallel sequencing

GC-FID Gas Chromatography with Flame Ionization Detection

Real-Time PCR Real-Time Polymerase Chain Reaction