

**The Appendix is an integral part of
Certificate of Accreditation No. 392/2023 ze dne: 19/07/2023**

Accredited entity according to ČSN EN ISO 15189:2013:

Krajská zdravotní, a.s. - Masarykova nemocnice v Ústí nad Labem, o.z.

CAB Number 8226, Laboratory of the Department of Medical Genetics

Sociální péče 3316/12a, Severní Terasa, 400 11 Ústí nad Labem

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.kzcr.eu/cz/ul/pro-pacienty/zdravotnicka-pracoviste/genetika/>.

Examinations:

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/ equipment	Examined material	Degrees of freedom ¹
816 – Medical Genetics Laboratory					
1.	Examination of constitutional karyotype	Cytogenetic analysis	Published procedure	Biological material containing core DNA	A, B, D
2.	Examination of constitutional chromosomal aberrations	FISH	Published procedure; Commercial procedure	Biological material containing core DNA	A, B, D
3.	Examination of germline genome variants	PCR with fragment analysis	Commercial procedure	Biological material containing DNA	A, B, C, D
4.	Examination of germline genome variants	PCR with fragment analysis	Commercial procedure	Biological material containing DNA	A, B, C, D
5.	Examination of germline genome variants	QF-PCR	Commercial procedure	Biological material containing DNA	A, B, C, D
6.	Examination of germline genome variants	aCGH	Commercial procedure	Biological material containing DNA	A, B, D
7.	Examination of germline genome variants	PCR with fragment analysis	Commercial procedure	Biological material containing DNA	A, B, C, D

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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.

aCGH *Array Comparative Genome Hybridization*

DNA *Deoxyribonucleic Acid*

FISH *Fluorescence In Situ Hybridization*

PCR *Polymerase Chain Reaction*

QF-PCR *Quantitative Fluorescence Polymerase Chain Reaction*