The Appendix is an integral part of Certificate of Accreditation No. 150/2023 of 03/04/2023

Accredited entity according to ČSN EN ISO 15189:2013:

CENTRUM LÉKAŘSKÉ GENETIKY s.r.o.

CAB Number 8046, Center for Medical Genetics, Ltd. - Laboratory Novohradská 1806/68, 370 08 České Budějovice

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.clg.cz/Akreditace/

Examinations:

Ordinal number	Examination procedure name	Principle of examination	Identification of procedure/ equipment	Examined material	Degrees of freedom ¹				
816 – Medical Genetics Laboratory									
1.	Examination of constitutional karyotype	Conventional cytogenetic analysis	Published procedure	Biological material containing human DNA	A, B, D				
2.	Examination of constitutional chromosomal aberrations	FISH	Published procedure	Biological material containing human DNA	A, B, D				
3.	Examination of germline genome variants	PCR-RFLP	Published procedure	Biological material containing human DNA	A, B, C, D				
4.	Examination of germline genome variants	Multiplex PCR	Published procedure	Biological material containing human DNA	A, B, C, D				
5.	Examination of germline genome variants	Reverse hybridization	Commercial procedure	Biological material containing human DNA	A, B, C, D				
6.	Examination of germline genome variants	PCR – capillary electrophoresis	Commercial procedure	Biological material containing human DNA	A, B, C, D				
7.	Examination of germline genome variants	Real-Time PCR	Commercial procedure	Biological material containing human DNA	A, B, C, D				
8.	Examination of germline genome variants	Sanger sequencing	Published procedure; In-house procedure	Body fluids	A, B, C, D				
9.	Examination of germline genome variants	NGS	Published procedure; In-house procedure	Body fluids	A, B, C, D				

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Ordinal number	Examination procedure name	Principle of examination	Identification of procedure/ equipment	Examined material	Degrees of freedom ¹
10.	Fragile X syndrome	TP-PCR	Commercial procedure	Body fluids	A, B, D
11.	Examination of germline genome variants	MLPA	Commercial procedure	Body fluids	A, B, C, D
12.	Examination of germline genome variants	aCGH	Commercial procedure	Biological material containing human DNA	A, B, C, D
13.	Non-invasive prenatal testing (NIPT)	NGS	Commercial procedure	Body fluids	A, B, C, D
14.	Examination of HLA system	SSP-PCR	Commercial procedure	Body fluids	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.

aCGH array Comparative Genome Hybridization

FISH Fluorescent In Situ Hybridization

MLPA Multiplex Ligation-dependent Probe Amplification

NGS Massive Parallel Sequencing
PCR Polymerase Chain Reaction

Real-Time PCR Quantitative Polymerase Chain Reaction

RFLP Restriction Fragment Length Polymorphism

SSP-PCR Polymerase Chain Reaction with Sequence Specific Primers

TP-PCR Triplet Primed Repeat PCR