The Appendix is an integral part of Certificate of Accreditation No. 455/2024 of 05/09/2024

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

Cytogenetická laboratoř Brno, s.r.o.

CAB Number 8067, Cytogenetic Laboratory Brno Veveří 476/39, 602 00 Brno - střed

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.cytogenetika.cz/ke-stazeni/

Examinations:

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of method procedure/ equipment	Examined material	Degrees of freedom ¹				
816 – Medical Genetics Laboratory									
1.	Examination of constitutional karyotype	Conventional cytogenetic analysis	Commercial procedure	Amniotic fluid, peripheral blood, umbilical blood, chorionic villi, tissue of aborted fetus, cultivated tissue culture	A, B				
2.	Examination of germline genome variants	PCR with fragment analysis	Commercial procedure	Biological material containing nuclear DNA	A, B, C, D				
3.	Examination of germline genome variants	PCR with fragment analysis	Commercial procedure	Biological material containing nuclear DNA	A, B, C, D				
4.	Examination of germline genome variants	NGS-MPS	Commercial procedure	Biological material containing nuclear DNA	A, B, C, D				
5.	Examination of germline genome variants	HRM	Commercial procedure	Biological material containing nuclear DNA	A, B, C, D				
6.	Examination of germline genome variants	MLPA	Commercial procedure	Biological material containing nuclear DNA	A, B, C, D				

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Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of method procedure/ equipment	Examined material	Degrees of freedom ¹
7.	Examination of unbalanced chromosomal aberrations	aCGH	Commercial procedure	Biological material containing nuclear DNA	A, B, C, D
8.	Non-invasive prenatal test (NIPT) of genomic variants	NGS-MPS	Commercial procedure	Biological material containing nuclear DNA	A, B, C, D
9.	Examination of germline genome variants	dTP-PCR	Commercial procedure	Biological material containing nuclear DNA	A, B, C, D
10.	Examination of germline genome variants	Real-Time PCR	Commercial procedure	Biological material containing nuclear DNA	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.

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MLPA Multiplex Ligation-Dependent Probe Amplification

NGS-MPS Massive parallel sequencing (Next Generation Sequencing – NGS)

HRM High Resolution Melting Curve Analysis

QF PCR Quantitative Fluorescence Polymerase Chain Reaction

ARMS Allele-specific amplification

Real-Time PCR Real-Time Polymerase Chain Reaction dTP-PCR Direct Triplet-Primed PCR method

aCGH Array Comparative Genomic Hybridisation

"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."