

The Appendix is an integral part of
Certificate of Accreditation No. 118/2024 of 11/03/2024

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

GENvia, s.r.o.
CAB Number 8006, Laboratory of Medical Genetics
Sýkovecká 276/54, 198 00 Praha 9 - Kyje

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 www.genvia.eu/akreditace.

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; In-house procedure	Nasopharyngeal, oropharyngeal and nasal swab, saliva, sputum, oral cavity lavage, tracheal aspirate, BAL	A, B
816 – Medical Genetics Laboratory					
1.	Examination of constitutional karyotype	Conventional cytogenetic analysis	Published procedure; In-house procedure	Amniotic fluid, fetal blood, peripheral blood, chorion, aborted tissue	A, B
2.	Examination of constitutional chromosomal aberrations	FISH	Published procedure; In-house procedure	Amniotic fluid, fetal blood, peripheral blood, chorion, aborted tissue, blastomere	A, B
3.	Examination of germline genome variants	PCR with fragment analysis	Commercial procedure; Published procedure; In-house procedure	Biological material containing genomic DNA	A, B, C
4.	Examination of germline genome variants	QF PCR	Commercial procedure; In-house procedure	Biological material containing genomic DNA	A, B, C
5.	Examination of germline genome variants	aCGH	Commercial procedure	Biological material containing genomic DNA	A, B



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6.	Examination of germline genome variants	MLPA	Commercial procedure; In-house procedure	Biological material containing genomic DNA	A, B, C
7.	Examination of germline genome variants	NGS-MPS	Commercial procedure; In-house procedure	Biological material containing genomic DNA	A, B, C
8.	Examination of germline genome variants	Real-Time PCR	Commercial procedure	Biological material containing genomic DNA	A, B, C
9.	Examination of germline genome variants	Sanger sequencing	Commercial procedure; In-house procedure	Biological material containing genomic DNA	A, B, C
10.	Examination of germline genome variants	PCR with electrophoretic detection	Commercial procedure	Biological material containing genomic DNA	A, B, C

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 Oligonucleotide array comparative genomic hybridization

FISH Fluorescence In Situ Hybridization

MLPA Multiplex Ligation-Dependent Probe Amplification

NGS-MPS Massively Parallel Sequencing

QF PCR Quantitative Fluorescence PCR

PCR Polymerase Chain Reaction

Real-Time PCR Polymerase Chain Reaction in real time

