

**The Appendix is an integral part of
Certificate of Accreditation No. 10/2024 of 11/01/2024**

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

SANATORIUM Helios, spol. s r.o.
CAB Number 8258, Laboratoř lékařské genetiky
Štefánikova 75/8, Ponava, 602 00 Brno

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.sanatoriumhelios.cz/laborator-lekarske-genetiky>.*

Examinations:

Ordinal Number	Analyt/parameter/diagnostics	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	Commercial procedure	Peripheral blood	A, B
2.	Examination of chromosomal aberrations	FISH	Commercial procedure	Peripheral blood	A, B
3.	Preimplantation genetic testing of genome variants (PGT)	PCR with fragment analysis	Commercial procedure; Published procedure	Biological material containing genomic DNA	A, B, C, D
4.	Examination of chromosome aneuploidy	NGS-MPS	Commercial procedure	Trophoblast	A, B

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.

PCR – Polymerase Chain Reaction

FISH – Fluorescence *In Situ* Hybridization

NGS-MPS – Massively Parallel Sequencing