

**The Appendix is an integral part of
Certificate of Accreditation No. 124/2024 of 14/03/2024**

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

PRONATAL s.r.o.
CAB Number: 8184, Genetic Laboratory PRONATAL
Roškotova 1717/2, 140 00 Praha 4

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://pronatal.cz/en/certificates>*

Examinations:

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of method procedure/ equipment	Examined material	Degrees of freedom ¹
802 – Medical Microbiology					
1.	Detection of nucleic acid of infectious agents	Real-Time PCR	Commercial procedure	Clinical material	A, B, C, D
816 – Medical Genetics Laboratory					
1.	Examination of constitutive chromosomal aberrations	FISH	Published procedure; In-house procedure	Peripheral blood, umbilical blood, amniotic fluid, chorionic villi and aborted tissue	A, B
2.	Examination of constitutive karyotype	Conventional cytogenetic analysis	Published procedure; In-house procedure	Peripheral blood, umbilical blood, amniotic fluid, chorionic villi and aborted tissue	A, B
3.	Examination of acquired chromosomal aberrations	Microscopy	Published procedure; In-house procedure	Peripheral blood lymphocytes	A, B
4.	Examination of germline genome variants	Real-Time PCR	Commercial procedure	Biological material containing human nuclear DNA	A, B, C, D
5.	Examination of germline genome variants	Fluorescent multiplex PCR method with subsequent fragment analysis	Published procedure; In-house procedure	Biological material containing human 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
6.	Preimplantation genetic testing of germline genome variants (PGT)	NGS-MPS	Commercial procedure	Biological material containing genomic DNA	A, B, C, D
7.	Preimplantation genetic testing of germline genome variants (PGT)	PGH method with subsequent fragment analysis	Published procedure; In-house procedure	Biological material containing genomic DNA	A, B, C, D
8.	Examination of germline genome variants	NGS-MPS	Commercial procedure	Biological material containing human nuclear DNA	A, B, C, D
9.	Examination of germline genome variants	MLPA	Commercial procedure	Biological material containing human nuclear DNA	A, B, C, D
10.	Examination of germline genome variants	Direct sequencing (Sanger)	Commercial procedure; In-house procedure	Biological material containing human 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.

AZF Azoospermic Factor

FISH Fluorescent In situ Hybridization

MLPA Multiplex Ligation-dependent Probe Amplification

NGS Next Generation Sequencing

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PCR	Polymerase Chain Reaction
PGH	Preimplantation genetic haplotyping
PGT-A	Preimplantation genetic testing for aneuploidy
PGT-M	Preimplantation genetic testing for monogenic diseases
PGT-SR	Preimplantation genetic testing for structural rearrangements
SMN1	Survival motor neuron 1 gene