

**The Appendix is an integral part of  
Certificate of Accreditation No. 134/2023 of 27/03/2023**

**Accredited entity according to ČSN EN ISO 15189:2013:**

**Genetika Plzeň, s.r.o.**  
CAB Number 8034, Genetics Laboratory  
Parková 1254/11a, Černice, 326 00 Plzeň

*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.genetika-plzen.cz/%23>.*

**Examinations:**

Ordinal number	Analyte/parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom <sup>1</sup>
<b>813 - Allergology and Immunology Laboratory</b>					
1.	Autoantibodies against phospholipids	Immunoassay with photometric detection	Commercial procedure	Serum	A, B, C
2.	Antisperm antibodies	Agglutination	Commercial procedure	Ejaculate, serum, ovulatory secretion	A, B
3.	Sperm acrosomes	Indirect immunofluorescence	Published procedure	Ejaculate	A, B
4.	Anti-spermatozoa antibodies	Agglutination	Published procedure	Serum	A, B
5.	Anti-ovarian and anti-zonal antibodies	Indirect immunofluorescence	Commercial procedure	Serum	A, B, C
<b>816 - Medical Genetics Laboratory</b>					
1.	Examination of germline genome variants	aCGH	Commercial procedure	Peripheral and fetal blood, buccal smear, amniotic fluid, chorionic villi and aborted tissue	A, B
2.	Examination of constitutional karyotype	Cytogenetic analysis	Published procedure	Peripheral and fetal blood, buccal smear, amniotic fluid, chorionic villi and aborted tissue	A, B
3.	Examination of constitutional chromosomal aberrations	FISH	Commercial procedure	Peripheral and fetal blood, buccal smear, amniotic fluid, chorionic villi and aborted tissue, blastomere, trophoctoderm	A, B
4.	Preimplantation genetic testing (PGT) of germline genome	NGS	Commercial procedure	Biological material containing human DNA	A, B, D

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Ordinal number	Analyte/parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom <sup>1</sup>
5.	Examination of germline genome variants	AS PCR	In-house procedure; Commercial procedure	Biological material containing human DNA	A, B, C, D
6.	Examination of germline genome variants	Multiplex PCR	In-house procedure; Commercial procedure	Biological material containing human DNA	A, B, C, D
7.	Examination of germline genome variants	QF PCR	In-house procedure	Peripheral and fetal blood, buccal swab, amniotic fluid (native and cultured), chorionic villi (native and cultured), aborted tissue	A, B, C
8.	Examination of germline genome variants	Real-time PCR	Commercial procedure	Peripheral blood, buccal smear	A, B
9.	Examination of germline genome variants	PCR with fragment analysis	Commercial procedure	Peripheral and fetal blood, buccal swab, amniotic fluid (native and cultured), chorionic villi (native and cultured), aborted tissue	A, B
10.	Examination of germline genome variants	Sanger sequencing	In-house procedure	Peripheral blood, buccal swab, amniotic fluid (native and cultured), chorionic villi (native and cultured), aborted tissue	A, B, C
11.	Examination of germline genome variants	MLPA	Commercial procedure	Peripheral blood, buccal swab, amniotic fluid (native and cultured), chorionic villi (native and cultured), aborted tissue	A, B, C

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Ordinal number	Analyte/parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom <sup>1</sup>
12.	Examination of germline genome variants	NGS	Commercial procedure	Biological material containing human DNA	A, B, C, D
<b>Laboratory examination for IVF</b>					
1.	Examination of spermiogram	Microscopy; Macroscopy	Published procedure	Ejaculate	A, B

**Explanatory notes:**

<sup>1</sup> Established degrees of freedom according to MPA 00-09-...:

A – Flexibility concerning the documented examination/collection procedure

B – Flexibility concerning technique

C – Flexibility concerning analytes/parameters

D – Flexibility concerning the material to be examined

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
AS PCR	Allele-Specific Polymerase Chain Reaction
CGG	Repetitions of nucleotides cytosine (C) and guanine (G)
FISH	Fluorescent In Situ Hybridization
MLPA	Multiplex Ligation-dependent Probe Amplification
NGS	Next-Generation Sequencing / Massive Parallel Sequencing
PCR	Polymerase Chain Reaction
PGT-A	Preimplantation Genetic Testing for Aneuploidies
PGT-SR	Preimplantation Genetic Testing for familial Structural chromosomal Rearrangements
QF PCR	Quantitative- Fluorescent Polymerase Chain Reaction
STR	Short Tandem Repeat