

**The Appendix is an integral part of
Certificate of Accreditation No. 374/2023 of 13/07/2023**

Accredited entity according to ČSN EN ISO 15189:2013:

GENNET, s.r.o.
CAB Number 8068, GENNET Laboratories
Kostelní 292/9, 170 00 Praha 7

Medical laboratory locations:

- | | | |
|----|---|-----------------------------------|
| 1. | Molecular Genetics Laboratory | Pekařská 635/6, 158 00 Praha 5 |
| 2. | Cytogenetics Laboratory - Pekařská | Pekařská 635/6, 158 00 Praha 5 |
| 3. | PGT Laboratory | Pekařská 635/6, 158 00 Praha 54. |
| | Cytogenetics Laboratory – Liberec | Liliová 118/1, 460 01 Liberec |
| 5. | IVF Laboratory – Liberec | Liliová 118/1, 460 01 Liberec |
| 6. | IVF Laboratory – Letná | Kostelní 292/9, 170 00 Praha 7 |
| 7. | IVF Laboratory – Archa | Na Poříčí 1046/24, 110 00 Praha 1 |
| 8. | Immunology Laboratory | Na Poříčí 1046/24, 110 00 Praha 1 |

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.gennet.cz/dokumenty-k-akreditaci-laboratori and www.gntlabs.cz/en/accreditation

1. Molecular Genetics Laboratory

Examinations:

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/ equipment	Examined material	Degrees of freedom ¹
816 – Medical Genetics Laboratory					
1.	Examination of germline genomic variants	Real-Time PCR	Commercial procedure; In-house procedure	Biological material containing genomic DNA	A, B, C, D
2.	Examination of germline genomic variants	PCR followed by fragment analysis	Commercial procedure; In-house procedure	Biological material containing genomic DNA	A, B, C, D
3.	Examination of germline genomic variants	PCR followed by sequencing analysis	In-house procedure	Biological material containing genomic DNA	A, B, C, D
4.	Examination of germline genomic variants	NGS	In-house procedure	Biological material containing genomic DNA	A, B, C, D
5.	Non-invasive prenatal test of chromosomal aneuploidies (NIPT)	NGS	In-house procedure	Peripheral blood	A, B, C

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2. Cytogenetics Laboratory - Pekařská

Examinations:

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/ equipment	Examined material	Degrees of freedom ¹
816 – Medical Genetics Laboratory					
1.	Examination of constitutional karyotype	Cytogenetic analysis of G-banded slides	Published procedure	Peripheral blood, umbilical blood, amniotic fluid, chorionic villi	A, B
2.	Examination of chromosomal aberrations	FISH	Commercial procedure; Published procedure	Peripheral blood, umbilical blood, amniotic fluid, chorionic villi	A, B
3.	Examination of unbalanced chromosomal aberrations and germinal genome	SNP array	Commercial procedure	Biological material containing genomic DNA	A, B

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3. PGT Laboratory

Examinations:

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/ equipment	Examined material	Degrees of freedom ¹
816 – Medical Genetics Laboratory					
1.	Preimplantation genetic testing of monogenic diseases and aneuploidies	Karyomapping	Commercial procedure; In-house procedure	Biological material containing genomic DNA	A, B, C, D
2.	Preimplantation genetic testing of aneuploidies	NGS	In-house procedure	Biological material containing genomic DNA	A, B, C, D

4. Cytogenetics Laboratory - Liberec

Examinations:

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/ equipment	Examined material	Degrees of freedom ¹
816 – Medical Genetics Laboratory					
1.	Examination of constitutional karyotype	Cytogenetic analysis of G-banded slides	Published procedure	Peripheral blood, umbilical blood	A, B

5. IVF Laboratory – Liberec

Examinations:

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/ equipment	Examined material	Degrees of freedom ¹
Laboratory examinations for IVF					
1.	Evaluation of ejaculate	Microscopic; Macroscopic	Published procedure	Human semen - ejaculate	A, B

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6. IVF Laboratory – Letná

Examinations:

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/ equipment	Examined material	Degrees of freedom ¹
Laboratory examinations for IVF					
1.	Evaluation of ejaculate	Microscopic; Macroscopic	Published procedure	Human semen - ejaculate	A, B

7. IVF Laboratory – Archa

Examinations:

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/ equipment	Examined material	Degrees of freedom ¹
Laboratory examinations for IVF					
1.	Evaluation of ejaculate	Microscopic; Macroscopic	Published procedure	Human semen - ejaculate	A, B

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8. Immunology Laboratory

Examinations:

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/ equipment	Examined material	Degrees of freedom ¹
813 - Allergology and Immunology Laboratory					
1.	Immunoglobulins	Immunoturbidimetry	Commercial procedure	Serum, plasma	A, B, C
2.	Specific Proteins	Immunoturbidimetry	Commercial procedure	Serum, plasma	A, B, C
3.	Autoantibodies	Immunoassays with fluorimetric detection	Commercial procedure	Serum, plasma	A, B, C
4.	Autoantibodies	Indirect immunofluorescence	Commercial procedure	Serum, plasma	A, B, C
5.	Specific IgE	Immunoassays with fluorimetric detection	Commercial procedure	Serum, plasma	A, B, C
6.	Immunophenotyping of cell subpopulations	Flow cytometry	Commercial procedure	Blood	A, B, C
7.	Anti-Müllerian hormone (AMH)	Immunoassay with luminometric detection	Commercial procedure	Serum, plasma	A

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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

Real-Time PCR Real-Time Polymerase Chain Reaction

NGS Next Generation Sequencing, also known as massively parallel sequencing

FISH Fluorescent In Situ Hybridization

SNP Array Whole genome screening utilizing the known single-nucleotide-polymorphism