



EA MLA Signatory
Český institut pro akreditaci, o.p.s.
Hájkova 2747/22, Žižkov, 130 00 Praha 3

issues

according to section 16 of Act No. 22/1997 Coll., on technical requirements for products, as amended

CERTIFICATE OF ACCREDITATION

No. 534/2024

GENNET, s.r.o.
with registered office Kostelní 292/9, 170 00 Praha 7,
Company Registration No. 27080234

for the Medical Laboratory No. **8068**
GENNET Laboratories

Scope of accreditation:

Cytogenetic and molecular genetic examinations including preimplantation genetic testing of embryos, laboratory andrology for IVF and examinations in allergy and clinical immunology to the extent as specified in the appendix to this Certificate.

This Certificate of Accreditation is a proof of Accreditation issued on the basis of assessment of fulfillment of the accreditation criteria in accordance with

ČSN EN ISO 15189 ed. 2:2013


In its activities performed within the scope and for the period of validity of this Certificate, the Conformity Assessment Body is entitled to refer to this Certificate, provided that the accreditation is not suspended and the Accredited Body meets the specified accreditation requirements in accordance with the relevant regulations applicable to the activity of an accredited Conformity Assessment Body.

This Certificate of Accreditation replaces, to the full extent, Certificate No.: 374/2023 of 13/07/2023, or any administrative acts building upon it.

The Certificate of Accreditation is valid until: **28/03/2027**

Prague: 10/10/2024




Milena Lochmanová
Director of the Department
of Medical Laboratories
Czech Accreditation Institute

**The Appendix is an integral part of
Certificate of Accreditation No. 534/2024 of 10/10/2024**

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

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 5 |
| 4. | 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.gnilabs.cz/akreditace.

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 genome variants	Real-Time PCR	Commercial procedure; In-house procedure	Biological material containing genomic DNA	A, B, C, D
2.	Examination of germline genome variants	PCR followed by fragment analysis	Commercial procedure; In-house procedure	Biological material containing genomic DNA	A, B, C, D
3.	Examination of germline genome variants	PCR followed by sequencing analysis	In-house procedure	Biological material containing genomic DNA	A, B, C, D
4.	Examination of germline genome 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	Conventional cytogenetic analysis	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	Conventional cytogenetic analysis	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	Microscopy; Macroscopy	Published procedure	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	Microscopy; Macroscopy	Published procedure	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	Microscopy; Macroscopy	Published procedure	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	Immunoassay with fluorimetric detection	Commercial procedure	Serum, plasma	A, B, C
6.	Immunophenotyping of cell populations	Flow cytometry	Commercial procedure	Blood	A, B, C
7.	Anti-Müllerian hormone (AMH)	Immunoassay with luminometric detection	Commercial procedure	Serum, plasma	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

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

"This document is an appendix to the certificate of accreditation. In case of any discrepancies between the English and Czech versions, the Czech version shall prevail, both for the certificate appendix and the certificate itself."