



EA MLA Signatory
Český institut pro akreditaci, o.p.s.
Olšanská 54/3, 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. 134/2023

Genetika Plzeň, s.r.o.
with registered office Parková 1254/11a, Černice, 326 00 Plzeň,
Company Registration No. 26357623

to the Medical laboratory No. **8034**
Genetics Laboratory

Scope of accreditation:

Examinations in the field of cytogenetics and molecular genetics, andrological examination of spermogram and reproductive immunology examinations in the field of allergology 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 15189:2013

In its activities performed within the scope and for the period of validity of this Certificate, the Body is entitled to refer to this Certificate, provided that the accreditation is not suspended and the 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.: 692/2021 of 22. 12. 2021, or any administrative acts building upon it.

The Certificate of Accreditation is valid until: 13. 8. 2025

Prague: 27. 3. 2023



Milena Lochmanová
Director of the Department of Medical Laboratories
Czech Accreditation Institute
Public Service Company

**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 ¹ |
|--|--|--|---------------------------------------|---|---------------------------------|
| 813 - Allergology and Immunology Laboratory | | | | | |
| 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 |
| 816 - Medical Genetics Laboratory | | | | | |
| 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 ¹ |
|----------------|---|----------------------------|---|--|---------------------------------|
| 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 ¹ |
|---------------------------------------|---|---------------------------|---------------------------------------|--|---------------------------------|
| 12. | Examination of germline genome variants | NGS | Commercial procedure | Biological material containing human DNA | A, B, C, D |
| Laboratory examination for IVF | | | | | |
| 1. | Examination of spermogram | Microscopy; Macroscopy | Published procedure | Ejaculate | A, B |

Explanatory notes:

¹ 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.

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|--------|--|
| 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 |

