



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

issues

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

CERTIFICATE OF ACCREDITATION

No. **389/2025**

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

for 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 ed. 3:2023

In its activities performed within the scope and for the period of validity of this Certificate, the abovementioned Accredited 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.: 134/2023 of 27/03/2023, and/or any administrative acts building upon it.

The Certificate of Accreditation is valid until: **25/07/2030**

Prague: 25/07/2025



Signed in the Czech original:
Milena Lochmanová on 25/07/2025

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

This translation of the Czech original has been issued by: Jana Chvalovská

**The Appendix is an integral part of
Certificate of Accreditation No. 389/2025 of 25/07/2025**

Accredited entity according to ČSN EN ISO 15189 ed. 3:2023:

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/seznam-cinnosti-v-ramci-flexibilniho-obsahu/>

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.	Antibodies	Immunoassay with photometric detection	Commercial procedure	Serum	A, B, C
2.	Antisperm antibodies	Agglutination	Commercial procedure	Ejaculate, serum	A, B
3.	Sperm acrosomes	Indirect immunofluorescence	Published procedure	Ejaculate	A, B
4.	Anti-ovarian, anti-zonal and anti-spermatozoa antibodies	Indirect immunofluorescence	Commercial procedure	Serum	A, B, C
816 – Medical Genetics Laboratory					
1.	Examination of unbalanced chromosomal aberrations	aCGH	Commercial procedure	Peripheral and fetal blood, buccal smear, amniotic fluid, chorionic villi and aborted tissue	A, B
2.	Examination of constitutional karyotype	Conventional cytogenetic analysis	Commercial procedure	Peripheral and fetal blood, buccal smear, amniotic fluid, chorionic villi and aborted tissue	A, B

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Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
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
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 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 blood, buccal swab, amniotic fluid (native and cultured), chorionic villi (native and cultured), aborted tissue	A, B

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Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
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
12.	Examination of germline genome variants	NGS	Commercial procedure	Biological material containing human DNA	A, B, C, D
Laboratory examinations for IVF					
1.	Examination of spermiogram	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 / sample collection procedure

B – Flexibility concerning the technique

C – Flexibility concerning the analytes / parameters

D – Flexibility concerning the examined material

E – Flexibility concerning the POCT delivery points

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)
FISH	Fluorescent In Situ Hybridization
MLPA	Multiplex Ligation-dependent Probe Amplification
NGS	New Generation Sequencing
PCR	Polymerase Chain Reaction
QF PCR	Quantitative- Fluorescent Polymerase Chain Reaction

"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. "