**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. **432/2025**

**CENTRUM LÉKAŘSKÉ GENETIKY s.r.o.**
**with registered office Novohradská 1806/68, 370 08 České Budějovice**
**Company Registration No. 26099764**

for the Medical Laboratory No. **8046**
Center for Medical Genetics, Ltd. - Laboratory

Scope of accreditation:

Examinations in the field of cytogenetics and molecular genetics 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.: 150/2023 of 03/04/2023, and/or any administrative acts building upon it.

The Certificate of Accreditation is valid until: **20/08/2030**

Prague: 20/08/2025

Český institut pro akreditaci, o.p.s. «ČAI»

Signed in the Czech original:
Milena Lochmanová on 20/08/2025

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. 432/2025 of 28/08/2025**

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

**CENTRUM LÉKAŘSKÉ GENETIKY s.r.o.**
CAB Number 8046, Center for Medical Genetics, Ltd. - Laboratory
Novohradská 1806/68, 370 08 České Budějovice

*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.clg.cz/Akreditace/ .

## Examinations:

| Ordinal number | Examination procedure name | 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 | Biological material containing human nuclear DNA | A, B, D |
| 2. | Examination of constitutional chromosomal aberrations | FISH | Published procedure | Biological material containing human nuclear DNA | A, B, D |
| 3. | Examination of germline genome variants | PCR-RFLP | Published procedure | Biological material containing human nucleic acid | A, B, C, D |
| 4. | Examination of germline genome variants | Multiplex PCR | Published procedure | Biological material containing human nucleic acid | A, B, C, D |
| 5. | Examination of germline genome variants | Reverse hybridization | Commercial procedure | Biological material containing human nucleic acid | A, B, C, D |
| 6. | Examination of germline genome variants | PCR – capillary electrophoresis | Commercial procedure | Biological material containing human nucleic acid | A, B, C, D |
| 7. | Examination of germline genome variants | Real-Time PCR | Commercial procedure | Biological material containing human nucleic acid | A, B, C, D |
| 8. | Examination of germline genome variants | Sanger sequencing | Published procedure; In-house procedure | Body fluids | A, B, C, D |
| 9. | Examination of germline genome variants | NGS-MPS | Published procedure; In-house procedure | Body fluids | A, B, C, D |
| 10. | Fragile X chromosome syndrome | TP-PCR | Commercial procedure | Body fluids | A, B, D |

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| Ordinal number | Examination procedure name | Principle of examination | Identification of procedure/ equipment | Examined material | Degrees of freedom[1] |
|---|---|---|---|---|---|
| 11. | Examination of germline genome variants | MLPA | Commercial procedure | Body fluids | A, B, C, D |
| 12. | Examination of germline genome variants | aCGH | Commercial procedure | Biological material containing human nucleic acid | A, B, C, D |
| 13. | Non-invasive prenatal testing of genome variants (NIPT) | NGS-MPS | Commercial procedure | Body fluids | A, B, C, D |
| 14. | Examination of HLA system | SSP-PCR | Commercial procedure | Body fluids | A, B, C, D |

## 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.

| | |
|---|---|
| aCGH | array Comparative Genome Hybridization |
| FISH | Fluorescent *In Situ* Hybridization |
| MLPA | Multiplex Ligation-dependent Probe Amplification |
| NGS-MPS | Massive Parallel Sequencing |
| PCR | Polymerase Chain Reaction |
| Real-Time PCR | Quantitative Polymerase Chain Reaction |
| RFLP | Restriction Fragment Length Polymorphism |
| SSP-PCR | Polymerase Chain Reaction with Sequence Specific Primers |
| TP-PCR | Triplet Primed Repeat PCR |

*"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. "*