



**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**



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 <sup>1</sup>
<b>816 – Medical Genetics Laboratory</b>					
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 <sup>1</sup>
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:**

<sup>1</sup> 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

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*"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. "*