



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. 150/2023

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

to the Medical laboratory No. **8046**
Centre 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 15189:2013

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.: 631/2021 of 2. 12. 2021, or any administrative acts building upon it.

The Certificate of Accreditation is valid until: **24. 8. 2025**

Prague: 3. 4. 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. 150/2023 of 03/04/2023**

Accredited entity according to ČSN EN ISO 15189:2013:

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 DNA	A, B, D
2.	Examination of constitutional chromosomal aberrations	FISH	Published procedure	Biological material containing human DNA	A, B, D
3.	Examination of germline genome variants	PCR-RFLP	Published procedure	Biological material containing human DNA	A, B, C, D
4.	Examination of germline genome variants	Multiplex PCR	Published procedure	Biological material containing human DNA	A, B, C, D
5.	Examination of germline genome variants	Reverse hybridization	Commercial procedure	Biological material containing human DNA	A, B, C, D
6.	Examination of germline genome variants	PCR – capillary electrophoresis	Commercial procedure	Biological material containing human DNA	A, B, C, D
7.	Examination of germline genome variants	Real-Time PCR	Commercial procedure	Biological material containing human DNA	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	Published procedure; In-house procedure	Body fluids	A, B, C, D



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Ordinal number	Examination procedure name	Principle of examination	Identification of procedure/ equipment	Examined material	Degrees of freedom ¹
10.	Fragile X syndrome	TP-PCR	Commercial procedure	Body fluids	A, B, D
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 DNA	A, B, C, D
13.	Non-invasive prenatal testing (NIPT)	NGS	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 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

