



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. 401/2023

REPROMEDA s.r.o.
with registered office Studentská 812/6, Bohunice, 625 00 Brno,
Company Registration No. 25557246

for the Medical Laboratory No. 8153
Laboratory of Medical and Reproductive Genetics

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

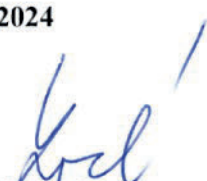
In its activities performed within the scope and for the period of validity of this Certificate, the Conformity Assessment Body is entitled to refer to this Certificate, provided that the accreditation is not suspended and the Accredited Body meets the specified accreditation requirements in accordance 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.: 99/2021 of 4. 2. 2021, or any administrative acts building upon it.

The Certificate of Accreditation is valid until: **31. 10. 2024**

Prague: 26. 7. 2023




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

**The Appendix is an integral part of
Certificate of Accreditation No. 20/2024 of 18/01/2024**

Accredited entity according to ČSN EN ISO 15189 ed 2:2013:

REPROMEDA s.r.o.

CAB Number 8153, Laboratory of Medical and Reproductive Genetics

Studentská 812/6, Bohunice, 625 00 Brno

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.repromedalab.cz/laboratorni-prirucka-a-certifikaty>

Examinations:

Ordinal Number	Analyte/ parameter/diagnostics	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	In-house procedure	Peripheral blood	A, B
2.	Examination of unbalanced chromosomal aberrations	NGS-MPS	Commercial procedure; In-house procedure	Biological material containing genomic DNA	A, B
3.	Reserved				
4.	Preimplantation genetic testing of germline genome variants (PGT)	Karyomapping	Commercial procedure; In-house procedure	Biological material containing genomic DNA	A, B, C
5.	Reserved				
6.	SMN1 gene examination	MLPA	Commercial procedure	Biological material containing genomic DNA	A, B
7.	Reserved				
8.	Examination of germline genome variants	NGS-MPS	Commercial procedure; In-house procedure	Biological material containing genomic DNA	A, B, C
9.	Reserved				
10.	Examination of germline genome variants	NGS-MPS	Commercial procedure; In-house procedure	Biological material containing genomic DNA	A, B, C

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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.

NGS-MPS Massively parallel sequencing

MLPA Multiplex ligation-dependent probe amplification

PCR Polymerase Chain Reaction