



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. 99/2021

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

to 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 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.: 570/2019 of 31. 10. 2019, or any administrative acts building upon it.

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

Prague: 4. 2. 2021



Milena Lochmanová
Director of the Department of Medical Laboratories
Czech Accreditation Institute
Public Service Company

Accredited entity according to ČSN EN ISO 15189:2013:

REPROMEDA s.r.o.
Laboratory of Medical and Reproductive Genetics
Studentská 812/6, Bohunice, 625 00 Brno

The Laboratory has a flexible scope of accreditation permitted as detailed in the Annex. Updated list of activities provided within the flexible scope of accreditation is available at the Laboratory from the Laboratory Manager.

Examinations:

Ordinal number	Examination procedure name	Examination procedure identification	Examined object
816 - Medical Genetics Laboratory			
1	Cytogenetic determination of karyotype by G banding method	SOP 00453	Peripheral blood
2	Preimplantation genetic examination of chromosomal aberrations by massive parallel sequencing method	SOP 00416	Blastomeres, polar bodies, trophoblast cells, biological material containing nuclear DNA
3	Reserved		
4	Preimplantation genetic examination by karyomapping method (*1)	SOP 00408	Blastomeres, polar bodies, trophoblast cells, peripheral blood, buccal smear, biological material containing nuclear DNA
5	Reserved		
6	Determination of copy number of exons 7 and 8 of SMN1 gene by MLPA method	SOP 00414	Peripheral blood, biological material containing nuclear DNA
7	Determination of the number of triplet repeats in FMR1 gene by TP-PCR method and fragment analysis	SOP 00415	Peripheral blood, biological material containing nuclear DNA
8	Panel diagnostic analysis of human genome variants by massive parallel sequencing method (*2)	SOP00417	Peripheral blood, biological material containing nuclear DNA
9	Preimplantation genetic examination by OneGene PGT method (*3)	SOP00420	Blastomeres, polar bodies, trophoblast cells, peripheral blood, buccal smear, biological material containing nuclear DNA

Annex:

Flexible scope of accreditation

Examination procedure ordinal numbers:
2,4,6-9

The Laboratory is allowed to modify the examination procedures listed in the Annex within the specified scope of accreditation provided the measuring principle is observed.

The flexible approach to the scope of accreditation cannot be applied to the examinations not included in the Annex.

