



## 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. 252/2025

Masarykova univerzita with registered office Žerotínovo náměstí 617/9, 602 00 Brno Company Registration No. 00216224

for the Medical Laboratory No. **8307**Genomics Core Facility of Centre for Molecular Medicine CEITEC MU

Scope of accreditation:

Laboratory diagnostics in the field of 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.: 44/2024 of 30/01/2024, and/or any administrative acts building upon it.

The Certificate of Accreditation is valid until: 30/01/2029

Prague: 30/05/2025





Signed in the Czech original: Milena Lochmanová on 30/05/2025

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. 252/2025 of 30/05/2025

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

# Masarykova univerzita

CAB Number 8307, Genomics Core Facility of Centre for Molecular Medicine CEITEC MU Kamenice 753/5, 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 <a href="http://clg.ceitec.cz/">http://clg.ceitec.cz/</a>.

#### **Examinations:**

| Ordinal<br>Number                 | Analyte/<br>parameter/diagnostics       | Principle of examination | Principle of examination | Examined material                                | Degrees<br>of<br>freedom <sup>1</sup> |
|-----------------------------------|---|--------------------------|--------------------------|--|---------------------------------------|
| 816 – Medical Genetics Laboratory |   |                          |                          |  |                                       |
| 1.                                | Examination of germline genome variants | NGS-MPS                  | Commercial procedure     | Biological material containing human genomic DNA | A, B, C,<br>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.

NGS-MPS Massively parallel sequencing

<sup>&</sup>quot;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."