



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. 682/2025

Fakultní nemocnice Hradec Králové
with registered office Sokolská 581, 500 05 Hradec Králové - Nový Hradec Králové
Company Registration No. 00179906

for the Medical Laboratory No. 8234
Molecular genetics laboratory of DCBD and DMG

Scope of accreditation:

Molecular genetic examinations of the human genome 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.: 509/2023 of 25/09/2023, and/or any administrative acts building upon it.

The Certificate of Accreditation is valid until: **19/12/2030**

Prague: 19/12/2025



Signed in the Czech original:
Milena Lochmanová on 19/12/2025

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. 682/2025 of 19/12/2025**

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

Fakultní nemocnice Hradec Králové
CAB Number 8234, Molecular genetics laboratory of DCBD and DMG
Sokolská 581, 500 05 Hradec Králové - Nový Hradec Králové

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.fnhk.cz/ukbd/zamereni-laboratore>*

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 unbalanced chromosomal aberrations | Array CGH | Commercial procedure | Biological material containing human nuclear DNA | A, B, D |
| 2. | HLA system examination | PCR with electrophoretic product detection | Commercial procedure | Biological material containing human nuclear DNA | A, B, C, D |
| 3. | Examination of germline genome variants | Methylation-specific MLPA | Published procedure; Commercial procedure | Biological material containing human nucleic acid | A, B, C, D |
| 4. | Examination of germline genome variants | Real-Time PCR | Published procedure; Commercial procedure | Biological material containing human nuclear DNA | A, B, C, D |
| 5. | Examination of germline genome variants | PCR with fragment analysis | Published procedure; Commercial procedure | Biological material containing human nuclear DNA | A, B, C, D |
| 6. | Examination of germline genome variants | MLPA | Published procedure; Commercial procedure | Biological material containing human nuclear DNA | A, B, C, D |
| 7. | Examination of germline genome variants | Direct sequencing (Sanger) | Published procedure | Biological material containing human nuclear DNA | A, B, C, D |
| 8. | Examination of germline genome variants | NGS-MPS | Commercial procedure; Published procedure | Biological material containing human nuclear DNA | A, B, C, D |
| 9. | Examination of somatic genome variants | NGS-MPS | Published procedure; In-house procedure | Biological material containing human nuclear DNA | A, B, C, D |

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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

E – Flexibility concerning the POCT delivery points

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 |
| MLPA | Multiplex Ligation-dependent Probe Amplification |
| NGS-MPS | Next Generation Sequencing - Massively Parallel Sequencing |
| PCR | Polymerase Chain Reaction |
| HLA | Major human histocompatibility complex (Human Leukocyte Antigens) |

"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."