



**EA MLA Signatory**  
**Český institut pro akreditaci, o.p.s.**  
**Hájkova 2747/22, Žižkov, 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. **501/2024**

**Unilabs Diagnostics k. s.**  
**with registered office Evropská 2589/33b, Dejvice, 160 00 Praha 6,**  
**Company Registration No. 60470488**

for the Medical Laboratory No. **8141**  
Laboratory of forensic and medical genetics

Scope of accreditation:

Examination 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 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.: 508/2023 of 25. 9. 2023, or any administrative acts building upon it.

The Certificate of Accreditation is valid until: **26. 9. 2029**

Prague: 26. 9. 2024



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

**The Appendix is an integral part of  
Certificate of Accreditation No. 501/2024 of 26/09/2024**

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

**Unilabs Diagnostics k. s.**  
CAB Number 8141, Laboratory of forensic and medical genetics  
Škrobárenská 502/1, 61700 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  
[www.unilabs.cz/cs/laboratore/genetika/AeskuLab-Brno](http://www.unilabs.cz/cs/laboratore/genetika/AeskuLab-Brno) .*

**Examinations:**

Ordinal Number	Analyte/parameter/diagnostics	Principle of examination	Identification of procedure/ equipment	Examined material	Degrees of freedom <sup>1</sup>
<b>816 – Medical Genetics Laboratory</b>					
1.	Examination of germline genome variants	Real-Time PCR	Commercial procedure; Published procedure	Biological material containing human nuclear DNA	A, B, C
2.	Examination of somatic genome variants	Real-Time PCR	Commercial procedure	Biological material containing human nuclear RNA	A, B, C
3.	Examination of germline genome variants	PCR with fragment analysis on gel	Commercial procedure; Published procedure	Biological material containing human nuclear DNA	A, B, C
4.	Examination of germline genome variants	PCR with fragment analysis (capillary electrophoresis)	Commercial procedure	Biological material containing human nuclear DNA	A, B, C
5.	Examination of germline genome variants	PCR with reverse hybridization	Commercial procedure	Biological material containing human nuclear DNA	A, B, C
6.	Examination of germline genome variants	Direct sequencing	Commercial procedure; Published procedure;	Biological material containing human nuclear DNA	A, B, C
7.	Examination of germline genome variants	MLPA	Commercial procedure	Biological material containing human nuclear DNA	A, B, C
8.	Examination of germline genome variants	NGS-MPS	Commercial procedure; Published procedure;	Biological material containing human nuclear DNA	A, B, C



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**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.

Real-Time PCR	Quantitative Real-Time Polymerase Chain Reaction
MLPA	Multiplex ligation-dependent probe amplification
NGS-MPS	Next Generation Sequencing - Massively Parallel Sequencing
PCR	Polymerase Chain Reaction

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*"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. "*

