



EA MLA Signatory
Český institut pro akreditaci, o.p.s.
Olišanská 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. 616/2023

Centrum kardiovaskulární a transplantační chirurgie Brno
with registered office Pekařská 664/53, Staré Brno, 602 00 Brno,
Company Registration No. 00209775

for the Medical Laboratory No. **8257**
Genetics Laboratory

Scope of accreditation:

Examinations in the field of molecular genetics, including shared examinations as defined in the Appendix to this Certificate 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

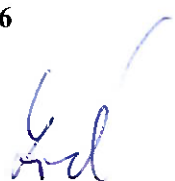
In its activities performed within the scope and for the period of validity of this Certificate, the Conformity Assessment Body is entitled to refer to this Certificate, provided that the accreditation is not suspended and the Accredited Body meets the specified accreditation requirements in accordance 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.: 230/2021 of 15. 4. 2021, or any administrative acts building upon it.

The Certificate of Accreditation is valid until: **15. 4. 2026**

Prague: 15. 11. 2023




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

**The Appendix is an integral part of
Certificate of Accreditation No. 616/2023 of 15/11/2023**

Accredited entity according to ČSN EN ISO 15189:2013:

Centrum kardiovaskulární a transplantační chirurgie Brno

CAB Number 8257, Genetics Laboratory

Výstavní 17/19, 603 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 www.cktch.cz/geneticka-laborator/d1019

Examinations:

Ordinal Number	Analyte/parameter/diagnostics	Principle of examination	Identification of procedure/ equipment	Examined material	Degrees of freedom ¹
802 – Medical Microbiology					
1.	Detection of nucleic acids of infectious agents	Real-Time PCR	Commercial procedure	Clinical material	A, B, C, D
816 – Medical Genetics Laboratory					
1.	Examination of germline genome variants	Sanger sequencing	In-house procedure	Biological material containing human DNA	A, B, C, D
2.	Examination of apolipoprotein B-100	ARMS; ACRS	In-house procedure	Biological material containing human DNA	A, B, D
3.	Examination of apolipoprotein E	PCR and restriction analysis	In-house procedure	Biological material containing human DNA	A, B, D
4.	Examination of germline genome variants	Real-Time PCR	Commercial procedure	Biological material containing human DNA	A, B, C, D
5.	Examination of germline genome variants	NGS-MPS	In-house procedure	Biological material containing human DNA	A, B, C, D

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.



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ARMS	Amplification Refractory Mutation System
ACRS	Amplification Created Restriction Site
NGS-MPS	Next Generation Sequencing – Massively Parallel Sequencing
PCR	Polymerase Chain Reaction
Real-Time PCR	Poly Chain Reaction in real time

