



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. **231/2024**

GHC GENETICS, s.r.o.
with registered office Krakovská 8/581, 110 00 Praha 1,
Company Registration No. 28188535

for the Medical Laboratory No. **8124**
GHC GENETICS Laboratory

Scope of accreditation:

Examination methods in the field of molecular genetics, medical microbiology and collection of primary samples 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.: 670/2023 of 15. 12. 2023, or any administrative acts building upon it.

The Certificate of Accreditation is valid until: **20. 5. 2029**

Prague: 20. 5. 2024




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

**The Appendix is an integral part of
Certificate of Accreditation No. 231/2024 ze of 20/05/2024**

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

GHC GENETICS, s.r.o.
CAB Number 8124, GHC GENETICS Laboratory
V Holešovičkách 1156/29, 182 00 Praha 8

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.ghccgenetics.cz/pro-lekare/ke-stazeni>.*

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	Biological material containing nucleic acid	A, B, C, D
2.	HIV markers	Immunoassay with luminometric detection	Commercial procedure	Serum, plasma	A, B
3.	Antibodies against infectious agent	Immunoassay with luminometric detection	Commercial procedure	Serum, plasma	A, B, C
4.	Antigens of infectious agents	Immunoassay with luminometric detection	Commercial procedure	Serum, plasma	A, B, C
5.	Reagin test (RPR)	Agglutination	Commercial procedure	Serum, plasma	A, B
813 - Laboratoř alergologická a imunologická					
1.	HLA system examination	PCR with reverse hybridization	Commercial procedure	Biological material containing nucleic acid	A, B, C, D
816 – Medical Genetics Laboratory					
1.	Examination of germline genome	Real-Time PCR	Commercial procedure; In-house procedure	Biological material containing nucleic acid	A, B, C, D
2.	Examination of germline genome	MLPA	Commercial procedure	Biological material containing nucleic acid	A, B, C, D
3.	Examination of germline genome	NGS-MPS	Commercial procedure; In-house procedure	Biological material containing nucleic acid	A, B, C, D

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Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
4.	Examination of somatic genome	NGS-MPS	Commercial procedure; In-house procedure	Biological material containing nucleic acid	A, B, C, D
5.	Examination of germline genome variants	PCR with fragment analysis	Commercial procedure; In-house procedure	Biological material containing nucleic acid	A, B, C, D
6.	HLA system examination	PCR with reverse hybridization	Commercial procedure	Biological material containing nucleic acid	A, B, C, D

Primary sample collection:

Ordinal Number	Sample collection technique	Identification of sample collection procedure	Collected material	Degrees of freedom ¹
1.	Venepuncture	Published procedure	Venous blood	A, B
2.	Buccal swab	Published procedure	Oral mucosa cells	A, B

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.

HLA Human Leucocyte Antigen

MLPA Multiplex Ligation-dependent Probe Amplification

NGS-MPS Massive parallel sequencing

PCR Polymerase Chain Reaction

Real-Time PCR Real-Time Polymerase Chain Reaction

