



#### 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. 467/2025

GHC GENETICS, s.r.o. with registered office Krakovská 581/8, 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 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.: 231/2024 of 20/05/2024, and/or any administrative acts building upon it.

The Certificate of Accreditation is valid until: 20/05/2029

Prague: 15/09/2025





Signed in the Czech original: Milena Lochmanová on 15/09/2025

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. 467/2025 of 15/09/2025

## 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 <a href="https://www.ghcgenetics.cz/pro-lekare/ke-stazeni">https://www.ghcgenetics.cz/pro-lekare/ke-stazeni</a> .

#### **Examinations:**

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom <sup>1</sup>				
802 – Medical Microbiology									
1.	Detection of nucleic acids of infectious agents	Real-Time PCR	Commercial procedure	Clinical material	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.	Non-specific antibodies against <i>Treponema pallidum</i>	Agglutination	Commercial procedure	Serum, plasma	A, B				
	813 - Allergology and Immunology Laboratory								
1.	HLA system examination	PCR with reverse hybridization	Commercial procedure	Biological material containing human 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 human nucleic acid	A, B, C, D				
2.	Examination of germline genome	MLPA	Commercial procedure	Biological material containing human 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 <sup>1</sup>
3.	Examination of germline genome	NGS-MPS	Commercial procedure; In-house procedure	Biological material containing human nucleic acid	A, B, C, D
4.	Examination of somatic genome	NGS-MPS	Commercial procedure; In-house procedure	Biological material containing human nucleic acid	A, B, C, D
5.	Examination of germline genome variants	PCR with fragment analysis	Commercial procedure; In-house procedure	Biological material containing human nucleic acid	A, B, C, D
6.	HLA system examination	PCR with reverse hybridization	Commercial procedure	Biological material containing human nucleic acid	A, B, C, D
7.	Examination of germline genome variants	Sanger sequencing	Commercial procedure; In-house procedure	Biological material containing human nucleic acid	A, B, C, D

### **Primary sample collection:**

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

## **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
  - 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.

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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

<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."