



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. 609/2025

Elphogene, s. r. o.
with registered office Drnovská 1112/60, Ruzyně, 161 00 Praha 6
Company Registration No. 07717067

for the Medical Laboratory No. **8279**
Elphogene

Scope of accreditation:

Examinations in the field of molecular genetics, including shared examinations 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.: 129/2023 of 21/03/2023, and/or any administrative acts building upon it.

The Certificate of Accreditation is valid until: 11/11/2026

Prague: 24/11/2025



Signed in the Czech original:
Marek Vyskočil on 24/11/2025

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. 609/2025 of 24/11/2025**

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

Elphogene, s. r. o.
CAB Number 8279, Elphogene
Drnovská 1112/60, Ruzyně, 161 00 Praha 6

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 somatic genome variants	PCR followed by separation of heteroduplexes by DCE	SOP 1, version no. 3	Histological preparations, bioptic tissues, peripheral blood, plasma	-

Specification of the scope of accreditation:

Field Nr. / Ordinal Number	Detailed information on activities within the scope of accreditation
816/1	<i>EGFR</i> gene – exon 19, 20, 21; <i>KRAS</i> gene - exon 2, 3, 4; <i>BRAF</i> gene – exon 15

Explanatory notes:

¹ The laboratory does not apply a flexible approach to the scope of accreditation

PCR Polymerase Chain Reaction

DCE Denaturing capillary electrophoresis (detection of PCR products under specific denaturing conditions)

"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."