



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. 409/2025

ELISABETH PHARMACON, spol. s r.o.
with registered office Rokycanova 4437/5, Židenice, 615 00 Brno
Company Registration No. 26258412

for the Medical Laboratory No. 8328
Elisabeth Pharmacon Diagnostic Laboratory Center

Scope of accreditation:

Laboratory diagnostics in the field of medical microbiology and primary sample collection 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.: 263/2025 of 03/06/2025, and/or any administrative acts building upon it.

The Certificate of Accreditation is valid until: 02/05/2026

Prague: 31/07/2025



Signed in the Czech original:
Milena Lochmanová on 03/06/2025

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. 409/2025 of 31/07/2025**

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

ELISABETH PHARMACON, spol. s r.o.
CAB Number 8328, Elisabeth Pharmacon Diagnostic Laboratory Center
Rokycanova 4437/5, Židenice, 615 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
<https://www.elilab.cz/dokumentace>*

Examinations:

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
802 – Medical Microbiology					
1.	HIV markers	Immunoassay with fluorescence detection	Commercial procedure	Serum, plasma	A, B
2.	Antibodies against infectious agents	Immunoassay with fluorescence detection	Commercial procedure	Serum, plasma	A, B, C
3.	Detection of nucleic acids of infectious agents	Real-Time PCR	Commercial procedure	Urine, urethral swab, semen	A, B, C
4.	Detection of nucleic acids of infectious agents	Real-Time PCR	Commercial procedure	Throat, nose, and nasopharynx swab	A, B, C

Odběr primárních vzorků:

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.	Swab	Published procedure	Throat, nose, and nasopharynx swab	A, B

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ELISABETH PHARMACON, spol. s r.o.
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Rokycanova 4437/5, Židenice, 615 00 Brno

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

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.

Real-Time PCR – Polymerase chain reaction in real time

"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. "