



**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. **207/2023**

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

to the Medical laboratory No. **8328**  
**ELISABETH PHARMACON Medical Laboratory**

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 15189:2013**

In its activities performed within the scope and for the period of validity of this Certificate, the Body is entitled to refer to this Certificate, provided that the accreditation is not suspended and the Body meets the specified accreditation requirements in accordance with the relevant regulations applicable to the activity of an accredited Conformity Assessment Body.

The Certificate of Accreditation is valid until: **2. 5. 2026**

Prague: 2. 5. 2023



**Milena Lochmanová**  
Director of the Department of Medical Laboratories  
Czech Accreditation Institute  
Public Service Company

**The Appendix is an integral part of  
Certificate of Accreditation No.207/2023 of 02/05/2023**

**Accredited entity according to ČSN EN ISO 15189:2013:**

**ELISABETH PHARMACON, spol. s r.o.**  
CAB Number 8328, ELISABETH PHARMACON Medical Laboratory  
Rokycanova 4437/5, Židenice, 615 00 Brno

**Examinations:**

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom <sup>1</sup>
<b>802 – Medical Microbiology</b>					
1.	HIV markers	Enzyme-Linked Fluorescent Assay	SOP 04.01 version 2; Mini VIDAS	Serum, plasma	-
2.	Antibodies against infectious agents	Enzyme-Linked Fluorescent Assay	SOP 04.01 version 2; Mini VIDAS	Serum, plasma	-
3.	Detection of nucleic acids originating from infectious agents	Real-Time PCR	SOP 04.02 version 2; CFX96, LC 480 II	Urine, urethral swab, semen	-
4.	Detection of nucleic acids originating from infectious agents	Real-Time PCR	SOP 04.02 version 2; CFX96, LC 480 II	Nasal, oral, nasopharyngeal, and/or oropharyngeal swab	-

**Specification of the scope of accreditation:**

Field Nr. / Ordinal Number	Detailed information on activities within the scope of accreditation
802/1	Antibodies against HIV 1, 2 and antigen p24 HIV
802/2	Antibodies against: SARS-CoV-2, class IgM and IgG; <i>Borrelia burgdorferi sensu lato</i> , class IgM and IgG
802/3	<i>Chlamydia trachomatis</i> , <i>Neisseria gonorrhoeae</i> , <i>Mycoplasma hominis</i> , <i>Mycoplasma genitalium</i> , <i>Ureaplasma urealyticum</i> , <i>Ureaplasma parvum</i> , <i>Gardnerella vaginalis</i> , <i>Trichomonas vaginalis</i>
802/4	Respiratory syncytial virus (RSV), SARS-CoV-2, Influenza viruses type A/B



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**Primary sample collection:**

Ordinal Number	Sample collection technique	Identification of sample collection procedure	Collected material	Degrees of freedom <sup>1</sup>
1.	Venepuncture	SOP 04.04 part A version 1	Venous blood	-
2.	Swab	SOP 04.04 part B version 1	Nasal, oral, nasopharyngeal, and/or oropharyngeal swab	-

**Explanatory notes:**

<sup>1</sup> The laboratory does not apply a flexible approach to the scope of accreditation

Real-Time PCR            quantitative polymerase chain reaction

