

**The Appendix is an integral part of
Certificate of Accreditation No. 260/2024 of 04/06/2024**

Accredited entity according to ČSN EN ISO 15189 ed. 2:2013:

ELISABETH PHARMACON, spol. s r.o.
CAB Number 8328, Elisabeth Pharmacon Diagnostic Laboratory Center
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 ¹
802 – Medical Microbiology					
1.	HIV markers	Immunoassay with fluorescence detection	SOP 04.01 version 2; Mini VIDAS	Serum, plasma	-
2.	Antibodies against infectious agents	Immunoassay with fluorescence detection	SOP 04.01 version 2; Mini VIDAS	Serum, plasma	-
3.	Detection of nucleic acids of infectious agents	Real-Time PCR	SOP 04.02 version 2; CFX96, LC 480 II	Urine, urethral swab, semen	-
4.	Detection of nucleic acids of infectious agents	Real-Time PCR	SOP 04.03 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 anti HIV 1,2 and Ag HIV p24;
802/2	Antibodies against: SARS-CoV-2 in class IgM and IgG; <i>Borrelia burgdorferi sensu lato</i> in 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 freedom¹
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:

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

Real-Time PCR Quantitative polymerase chain reaction

"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. "