

List of activities within the flexible scope of accreditation

Accredited Body: ELISABETH PHARMACON, spol. s r.o.
CAB Name: Elisabeth Pharmacon Diagnostic Laboratory Center
CAB Number: 8328
Certificate of Accreditation No.: 409/2025
Field of Accreditation: Medical laboratory - ČSN EN ISO 15189 ed. 3:2023
Updated: 31. 7. 2025

Examinations:

Ordinal Number	Analyte/parameter/diagnostics	Principle of examination	Identification of method procedure/ equipment	Examined material	Degrees of freedom ¹
802 – Medical Microbiology					
1.	HIV markers	Immunoassay with fluorescence detection	SOP 04.01, version 3; Mini VIDAS	Serum, plasma	A, B
2.	Antibodies against infectious agents	Immunoassay with fluorescence detection	SOP 04.01, version 3; Mini VIDAS	Serum, plasma	A, B, C
3.	Detection of nucleic acids of infectious agents	Real-Time PCR	SOP 04.02, version 3; CFX96; LC 480 II	Urine, urethral swab, semen	A, B, C
4.	Detection of nucleic acids of infectious agents	Real-Time PCR	SOP 04.03, version 3; CFX96; LC 480 II	Throat, nose, and nasopharynx swab	A, B, C

Specification of the scope of accreditation:

Field Nr. / Ordinal Number	Detailed information on activities within the scope of accreditation
802/1	Ab anti HIV 1,2 (Ig total) a 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	DNA <i>Chlamydia trachomatis</i> ; DNA <i>Neisseria gonorrhoeae</i> ; DNA <i>Mycoplasma hominis</i> ; DNA <i>Mycoplasma genitalium</i> ; DNA <i>Ureaplasma urealyticum</i> ; DNA <i>Ureaplasma parvum</i> ; DNA <i>Gardnerella vaginalis</i> ; DNA <i>Trichomonas vaginalis</i> ;

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Field Nr. / Ordinal Number	Detailed information on activities within the scope of accreditation
802/4	RNA Respiratory syncytial virus (RSV); RNA <i>SARS-CoV-2</i> ; RNA influenza viruses type A/B

Primary sample collection:

Ordinal Number	Sample collection technique	Identification of sample collection procedure	Collected material	Degrees of freedom ¹
1.	Venepuncture	SOP 04.04 part A, version 1	Venous blood	A, B
2.	Swab	SOP 04.04 part B, version 1	Throat, nose, and nasopharynx swab	A, B

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