

**The Appendix is an integral part of  
Certificate of Accreditation No. 486/2023 of 26. 09. 2023**

Accredited entity according to ČSN EN ISO 15189:2013:

**PREVEDIG medical, s.r.o.**  
CAB Number 8099, Laboratory Diagnostics centre  
Poznaňská 461/34, 181 00 Praha 8

**Medical laboratory locations:**

- |   |  |
|---|--|
| 1. <b>Biochemistry and Haematology Department</b> | Poznaňská 461/34, 181 00 Praha 8         |
| 2. <b>Microbiology Department</b>                 | Poznaňská 461/34, 181 00 Praha 8         |
| 3. <b>Immunology and Allergology Department</b>   | Poznaňská 461/34, 181 00 Praha 8         |
| 4. <b>Sampling Site Poznaňská</b>                 | Poznaňská 461/34, 181 00 Praha 8         |
| 5. <b>Sampling Site Městská poliklinika Praha</b> | Spálená 78/12, 110 00 Praha 1            |
| 6. <b>Sampling Site Poliklinika Revoluční</b>     | Revoluční 765/19, 110 00 Praha 1         |
| 7. <b>Sampling Site Poliklinika K-Centrum</b>     | Senovážné náměstí 980/22, 110 00 Praha 1 |
| 8. <b>Sampling Site Ženské domovy</b>             | Ostrovského 253/3, 150 00 Praha 5        |
| 9. <b>Sampling Site Žižkov – Olšanská</b>         | Olšanská 54/3, 130 00 Praha 3            |
| 10. <b>Sampling Site Černošice</b>                | Táborská 2025/132, 252 28 Černošice      |
| 11. <b>Sampling Site Lékařský dům Novodvorská</b> | Jílovská 1148/14, 143 00 Praha 4         |
| 12. <b>Sampling Site Poliklinika Palmovka</b>     | Zenklova 340/22, 182 00 Praha 8          |
| 13. <b>Sampling Site Poliklinika Rohožník</b>     | Živonínská 1630, 190 16 Praha 9          |
| 14. <b>Sampling Site Lety</b>                     | Pražská 459, 252 29 Lety u Dobřichovic   |
| 15. <b>Sampling Site Nad spádem</b>               | Nad spádem 641/20, 147 00 Praha 4        |

**1. Biochemistry and Haematology Department**

**Examinations:**

| Ordinal number                     | Analyte/parameter/diagnostics | Principle of examination | Identification of method procedure/equipment  | Examined material | Degrees of freedom <sup>1</sup> |
|------------------------------------|-------------------------------|--------------------------|---|-------------------|---------------------------------|
| <b>801 – Clinical Biochemistry</b> |                               |                          |   |                   |                                 |
| 1.                                 | Minerals                      | Potenciometry            | SOPV-PREV-56, version 02;<br>SOPV-PREV-57, version 02;<br>SOPV-PREV-58, version 02;<br>DxC 700 AU;<br>AU 5800 | Serum, urine      | -                               |

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| Ordinal number | Analyte/parameter/diagnostics      | Principle of examination                | Identification of method procedure/equipment   | Examined material    | Degrees of freedom <sup>1</sup> |
|----------------|------------------------------------|---|--|----------------------|---------------------------------|
| 2.             | Minerals                           | Absorption spectrophotometry            | SOPV-PREV-59, version 02;<br>SOPV-PREV-60, version 02;<br>SOPV-PREV-61, version 02;<br>SOPV-PREV-62, version 02;<br>DxC 700 AU;<br>AU 5800 | Serum, urine         | -                               |
| 3.             | Non-protein nitrogenous substances | Absorption spectrophotometry            | SOPV-PREV-43, version 02;<br>SOPV-PREV-46, version 02;<br>SOPV-PREV-63, version 02;<br>AU 5800   | Serum, urine         | -                               |
| 4.             | Proteins                           | Absorption spectrophotometry            | SOPV-PREV-68, version 02;<br>SOPV-PREV-69, version 02;<br>AU 5800  | Serum                | -                               |
| 5.             | Enzymes                            | Absorption spectrophotometry            | SOPV-PREV-38, version 02;<br>SOPV-PREV-39, version 02;<br>SOPV-PREV-42, version 02;<br>SOPV-PREV-66, version 02;<br>AU 5800; DxC 700 AU    | Serum                | -                               |
| 6.             | Lipids                             | Absorption spectrophotometry            | SOPV-PREV-47, version 02;<br>SOPV-PREV-48, version 02;<br>AU 5800  | Serum                | -                               |
| 7.             | Sacharides                         | Absorption spectrophotometry            | SOPV-PREV-40, version 02;<br>AU 5800   | Serum, plasma, urine | -                               |
| 8.             | Pigments                           | Absorption spectrophotometry            | SOPV-PREV-41, version 02;<br>AU 5800   | Serum                | -                               |
| 9.             | Vitamins                           | Immunoassay with luminometric detection | SOPV-PREV-41, version 01;<br>Liaison XL  | Serum                | -                               |

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| Ordinal number                                     | Analyte/parameter/diagnostics                          | Principle of examination                | Identification of method procedure/equipment  | Examined material | Degrees of freedom <sup>1</sup> |
|--|--|---|---|-------------------|---------------------------------|
| 10.  | Tumor markers  | Immunoassay with luminometric detection | SOPV-PREV-81, version 01;<br>SOPV-PREV-87, version 01;<br>SOPV-PREV-104, version 01;<br>SOPV-PREV-105, version 01;<br>DxI 800   | Serum             | -                               |
| 11.  | Markers for calculating the risk of congenital defects | Immunoassay with luminometric detection | SOPV-PREV-004, version 01;<br>SOPV-PREV-005, version 01;<br>SOPV-PREV-006, version 01;<br>SOPV-PREV-104, version 01;<br>SOPV-PREV-105, version 01;<br>KRYPTOR Compact Plus,<br>DxI          | Serum             | -                               |
| 12.  | Chemical examination of urine                          | Refractometry                           | SOPV-PREV-50, version 02;<br>UC-3500  | Urine             | -                               |
| 13.  | Glycated haemoglobin (HbA1c)                           | High-Performance Liquid Chromatography  | SOPV-PREV-88, version 01;<br>Tosoh G8   | Blood             | -                               |
| <b>813 - Allergology and Immunology Laboratory</b> |  |   |   |                   |                                 |
| 1.   | C-reactive protein                                     | Immunoturbidimetry                      | SOPV-PREV-070, version 02;<br>AU 5800   | Serum             | -                               |
| <b>815 - Nuclear Medicine Laboratory</b>           |  |   |   |                   |                                 |
| 1.   | Hormones   | Immunoassay with luminometric detection | SOPV-PREV-004, version 01;<br>SOPV-PREV-077, version 01;<br>SOPV-PREV-078, version 01;<br>SOPV-PREV-079, version 01;<br>SOPV-PREV-095, version 01;<br>SOPV-PREV-105, version 01;<br>DxI 800 | Serum             | -                               |

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| Ordinal number                      | Analyte/parameter/diagnostics | Principle of examination   | Identification of method procedure/equipment | Examined material | Degrees of freedom <sup>1</sup> |
|-------------------------------------|-------------------------------|--|--|-------------------|---------------------------------|
| <b>818 - Haematology Laboratory</b> |                               |  |  |                   |                                 |
| 1.                                  | Blood count                   | Impedance method;<br>Photometry;<br>Calculations                       | SOPV-PREV-54, version 04;<br>DxH 900         | Blood             | -                               |
| 2.                                  | Phrotrombin test              | Coagulation method with optical detection of coagulum;<br>Calculations | SOPV-PREV-83, version 02;<br>ACL TOP 750 LAS | Plasma            | -                               |

**Specification of the scope of accreditation:**

| Field Nr. / Ordinal Number | Detailed information on activities within the scope of accreditation   |
|----------------------------|--|
| 801/1                      | Na <sup>+</sup> , K <sup>+</sup> , Cl <sup>-</sup>   |
| 801/2                      | Total calcium, magnesium, iron, inorganic phosphate  |
| 801/3                      | Creatinin, urea nitrogen, uric acid  |
| 801/4                      | Total protein, albumin   |
| 801/5                      | Alanine aminotransferase, aspartate aminotransferase, gama glutamyl transferase, creatine kinase   |
| 801/6                      | Cholesterol total, triacylglyceroles   |
| 801/7                      | Glucose  |
| 801/8                      | Bilirubin total  |
| 801/9                      | 25-OH vitamin D  |
| 801/10                     | Carbohydrate tumor antigen (CA 19-9), total prostate-specific antigen (PSA total), alpha-fetoprotein (AFP), β-hCG  |
| 801/11                     | Chorionic gonadotropin-free fraction beta (freeβHCG), pregnancy-associated plasma protein A (PAPP-A), alpha-fetoprotein (AFP), β-hCG, unconjugated estriol |
| 801/12                     | Specific gravity, pH, protein, glucose, keton, urobilinogen, bilirubin, leukocytes, blood, nitrite   |
| 815/1                      | Unconjugated estriol, thyrotropin (TSH), thyroxine free (T4 volný), triiodothyronine free (T3 volný), prolactin, β-hCG                                     |

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| <b>Field Nr. /<br/>Ordinal<br/>Number</b> | <b>Detailed information on activities within the scope of accreditation</b>   |
|---|---|
| 818/1                                     | Leukocytes (WBC); Erythrocytes (RBC); Haemoglobin (HGB); Haematocrit (HCT); Mean corp. volume (MCV); Mean corp. haemoglobin (MCH); Mean corp. Haemoglobin Conc. (MCHC); Red cell distribution width (RDW); Plateles (PLT) |
| 818/2                                     | PT-time, PT-INR, PT-racio   |

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**2. Microbiology Department**

**Examinations:**

| Ordinal number                    | Analyte/parameter/diagnostics        | Principle of examination                | Identification of method procedure/equipment   | Examined material                                       | Degrees of freedom <sup>1</sup> |
|-----------------------------------|--------------------------------------|---|--|---|---------------------------------|
| <b>802 – Medical Microbiology</b> |                                      |   |  |   |                                 |
| 1.                                | Antibodies against infectious agents | Immunoassay with luminometric detection | SOPV-PREV-10, version 03;<br>SOPV-PREV-12, version 03;<br>SOPV-PREV-16, version 03;<br>SOPV-PREV-91, version 02;<br>SOPV-PREV-106, version 02;<br>SOPV-PREV-107, version 02;<br>Liaison XL | Serum, plazma   | -                               |
| 2.                                | Antibodies against infectious agents | Immunoassay with photometric detection  | SOPV-PREV-19, version 02;<br>DS2   | Serum, plazma   | -                               |
| 3.                                | Antigens of infectious agents        | Immunoassay with luminometric detection | SOPV-PREV-90, version 03;<br>SOPV-PREV-91, version 02;<br>Liaison XL   | Serum, plazma   | -                               |
| 4.                                | Antibodies against infectious agents | Immunoblotting                          | SOPV-PREV-10, version 03;<br>SOPV-PREV-19, version 02;<br>AutoBlot 3000  | Serum, plazma   | -                               |
| 5.                                | Reagin test (RPR)                    | Immunoturbidimetry                      | SOPV-PREV-107, version 02;<br>DxC 700 AU   | Serum, plazma   | -                               |
| 6.                                | Identification of bacteria           | Agglutination                           | SOPV-PREV-201, version 04  | Bacterial culture                                       | -                               |
| 7.                                | Identification of microorganisms     | Mass spectrometry                       | SOPV-PREV-201, version 04;<br>MALDI-TOF  | Bacterial culture, yeast culture and filamentous fungus | -                               |

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| Ordinal number | Analyte/parameter/diagnostics                                    | Principle of examination                                     | Identification of method procedure/equipment                          | Examined material   | Degrees of freedom <sup>1</sup> |
|----------------|--|--|---|---|---------------------------------|
| 8.             | Identification of microorganisms                                 | Phenotyping  | SOPV-PREV-201, version 04   | Bacterial culture, yeast culture and filamentous fungus   | -                               |
| 9.             | Qualitative examination of the sensitivity of microorganisms     | Disk diffusion test  | SOPV-PREV-202, version 05   | Bacterial culture, yeast culture and filamentous fungus   | -                               |
| 10.            | Quantitative examination of the sensitivity of microorganisms    | Microdilution test;<br>E-test                                | SOPV-PREV-202, version 05   | Bacterial culture, yeast culture and filamentous fungus   | -                               |
| 11.            | Detection of nucleic acid of infectious agents                   | Real-Time PCR (automatically)                                | SOPV-PREV-220, version 01;<br>SOPV-PREV-222, version 02;<br>GeneXpert | Serum, plasma nasopharyngeal swab   | -                               |
| 12.            | Detection of nucleic acid of infectious agents                   | Real-Time PCR  | SOPV-PREV-222, version 02;<br>MIC, DFX96 Touch                        | Swab from throat, nose, nasopharyngs, saliva, sputum  | -                               |
| 13.            | Microbiological examination of the upper respiratory tract       | Aerobic cultivation  | SOPV-PREV-204, version 03   | Swab from throat, nose, nasopharyngs, tonsil, pharynx, larynx   | -                               |
| 14.            | Microbiological examination of clinical material                 | Microscopy;<br>Aerobic cultivation;<br>Anaerobic cultivation | SOPV-PREV-205, version 03;<br>SOPV-PREV-221, version 01               | Swab from middle ear, external ear, eye, oral cavity, tongue, skin, leg ulcer, wound, decubitus, pus, abscess, fistula, exudate, perineum | -                               |
| 15.            | Microbiological examination of urine using a quantitative method | Aerobic cultivation  | SOPV-PREV-206, version 03   | Urine   | -                               |

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| Ordinal number | Analyte/parameter/diagnostics                                    | Principle of examination                                     | Identification of method procedure/equipment  | Examined material   | Degrees of freedom <sup>1</sup> |
|----------------|--|--|---|---|---------------------------------|
| 16.            | Microbiological examination of urine using a quantitative method | Turbidimetry   | SOPV-PREV-206, version 03;<br>UROQUATTRO HB&L | Urine   | -                               |
| 17.            | Microbiological examination of rectal swabs                      | Aerobic cultivation  | SOPV-PREV-207, version 03                     | Rectal swab   | -                               |
| 18.            | Microbiological examination urogenital tract                     | Microscopy;<br>Aerobic cultivation;<br>Anaerobic cultivation | SOPV-PREV-208, version 03                     | Vaginal swab,<br>cervical swab,<br>urethral swab,<br>prostatic secretion,<br>ejaculate, vulva,<br>IUT, glans penis,<br>prepuce swab | -                               |

**Specification of the scope of accreditation:**

| Field Nr. / Ordinal Number | Detailed information on activities within the scope of accreditation  |
|----------------------------|---|
| 802/1                      | <i>Borrelia burgdorferi. s.l.</i> of IgM a IgG class (S_Anti-Borrelia IgM, Anti Borrelia IgG);<br>CMV of IgM, IgG class and total (S_Anti-CMV IgM, S_Anti-CMV IgG, IgG);<br>EBV of IgM, IgG class (S_Anti EBV-CA IgM, S_Anti EBV-CA IgG, S_Anti EBV-EA IgG, S_Anti EBNA1 IgG);<br>HIV (S_Anti HIV.1/2);<br><i>Treponema pallidum</i> of IgG class (S_Anti Treponema pallidum IgG);<br>HCV total (S_HCV) |
| 802/2                      | <i>Helicobacter pylori</i> of IgA a IgG class (S_Anti-Helicobacter pylori IgA, S_Anti-Helicobacter pylori IgG)  |
| 802/3                      | HIV (p24 antigen);<br>Hepatitis B (S_HBsAg)   |
| 802/4                      | <i>Borrelia burgdorferi. s.l.</i> of IgM a IgG class (S_Anti-Borrelia IgM-WB, S_Anti-Borrelia IgG-WB);<br><i>Helicobacter pylori</i> of IgA a IgG class (S_Anti-Helicobacter- pylori IgA-WB, S_Anti-Helicobacter pylori IgG-WB)   |



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|        |   |
|--------|---|
| 802/6  | Beta hemolytic streptococci;<br>staphylococci;<br>salmonella serotyping<br>serotyping E. coli;<br>Neisseria meningitidis;<br>Shigella spp;<br>Yersinia enterocolitica |
| 802/7  | Bacteria, yeasts, filamentous fungi   |
| 802/8  | Bacteria, yeasts, filamentous fungi   |
| 802/9  | Bacteria, yeasts, filamentous fungi   |
| 802/10 | Bacteria, yeasts, filamentous fungi   |
| 802/11 | Hepatitis B virus DNA;<br>Hepatitis C virus RNA;<br>SARS-CoV-2 RNA;<br>Influenza A, B RNA;<br>RS virus RNA  |
| 802/12 | SARS-CoV-2 RNA;<br>Influenza A, B RNA;<br>RS virus RNA  |
| 802/13 | Bacteria, yeasts  |
| 802/14 | Bacteria, yeasts, filamentous fungi   |
| 802/15 | Bacteria, yeasts  |
| 802/16 | Bacteria, yeasts  |
| 802/17 | Bacteria, yeasts  |
| 802/17 | Bacteria, yeasts  |
| 802/18 | Bacteria, yeasts  |

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**3. Immunology and Allergology Department**

**Examinations:**

| Ordinal number                                     | Analyte/parameter/diagnostics         | Principle of examination                | Identification of method procedure/equipment  | Examined material | Degrees of freedom <sup>1</sup> |
|--|---------------------------------------|---|---|-------------------|---------------------------------|
| <b>813 - Allergology and Immunology Laboratory</b> |                                       |   |   |                   |                                 |
| 1.   | Immunoglobulins                       | Imunoturbidimetry                       | SOPV-PREV-192, version 02;<br>DxC 700 AU  | Serum             | -                               |
| 2.   | Autoantibodies                        | Indirect immunofluorescence             | SOPV-PREV-177, version 01;<br>SOPV-PREV-178, version 02;<br>SOPV-PREV-179, version 01;<br>SOPV-PREV-181, version 01;<br>SOPV-PREV-194, version 01;<br>QUANTA-Lyser; NIKON fluorescence microscope | Serum             | -                               |
| 3.   | Autoantibodies                        | Immunoassay with luminometric detection | SOPV-PREV-158, version 01;<br>SOPV-PREV-162, version 01;<br>BioFlash  | Serum             | -                               |
| 4.   | Rheumatoid Factor (RF)                | Imunoturbidimetry                       | SOPV-PREV-198, version 02;<br>DxC 700 AU  | Serum             | -                               |
| 5.   | Imunoglobulin E                       | Immunoassay with fluorimetric detection | SOPV-PREV-199, version 01;<br>UNICAP 250  | Serum             | -                               |
| 6.   | Specific IgE                          | Immunoassay with fluorimetric detection | SOPV-PREV-150, version 01;<br>UNICAP 250  | Serum             | -                               |
| 7.   | Immunophenotyping of cell populations | Flow cytometry                          | SOPV-PREV-151, version 01;<br>SOPV-PREV-173, version 01;<br>Navios  | Blood             | -                               |
| 8.   | Antibodies                            | Immunoassay with luminometric detection | SOPV-PREV-156, version 01;<br>SOPV-PREV-157, version 01;<br>BioFlash  | Serum             | -                               |

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**Specification of the scope of accreditation:**

| <b>Field Nr. /<br/>Ordinal<br/>Number</b> | <b>Detailed information on activities within the scope of accreditation</b>  |
|---|--|
| 813/1                                     | IgG, IgA, IgM  |
| 813/2                                     | ANA IgG, anti dsDNA IgG, AMA IgG, ASMA IgG, anti LKM IgG, ANCA IgG, anti EMA IgA, anti EMA IgG   |
| 813/3                                     | Anti PR3 IgG, anti MPO IgG, anti tTG IgA   |
| 813/4                                     | Rheumatoid factor (RF screen)  |
| 813/7                                     | Immunophenotyping of cell populations (%): T lymphocytes (CD3 <sup>+</sup> ), Th lymphocytes (CD3 <sup>+</sup> CD4 <sup>+</sup> ), Tc lymphocytes (CD3 <sup>+</sup> CD8 <sup>+</sup> ), B lymphocytes (CD19 <sup>+</sup> ), NK lymphocytes (CD3 <sup>+</sup> CD56 <sup>+</sup> ) |
| 813/8                                     | anti CCP IgG, DGP IgA, DGP IgG   |

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4. **Sampling Site Poznaňská**
5. **Sampling Site Městská poliklinika Praha**
6. **Sampling Site Poliklinika Revoluční**
7. **Sampling Site Poliklinika K-Centrum**
8. **Sampling Site Ženské domovy**
9. **Sampling Site Žižkov – Olšanská**
10. **Sampling Site Černošice**
11. **Sampling Site Lékařský dům Novodvorská**
12. **Sampling Site Poliklinika Palmovka**
13. **Sampling Site Poliklinika Rohožník**
14. **Sampling Site Lety**
15. **Sampling Site Nad spádem**

**Primary sample collection:**

| <b>Ordinal number</b> | <b>Sample collection technique</b> | <b>Identification of sample collection procedure</b> | <b>Collected material</b>      | <b>Degrees of freedom<sup>1</sup></b> |
|-----------------------|------------------------------------|--|--------------------------------|---------------------------------------|
| 1.                    | Venepuncture                       | PI-PREV-05, verze 01                                 | Venous blood                   | -                                     |
| 2.                    | Capillary puncture                 | PI-PREV-05, verze 01                                 | Capillary blood                | -                                     |
| 3.                    | Swab                               | PI-PREV-27, verze 01                                 | Swabs from the throat and nose | -                                     |

**Explanatory notes:**

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