

List of activities within the flexible scope of accreditation

Accredited Body: Centrum kardiiovaskulární a transplantační chirurgie Brno
CAB Name: Genetics laboratory
CAB Number: 8257
Certificate of Accreditation No.: 180/2026
Field of Accreditation: Medical Laboratories – ČSN EN ISO 15189 ed. 3:2023
Updated: 14. 4. 2026

Examinations:

| Ordinal Number | Analyte/ parameter/diagnostics | Principle of examination | Identification of method procedure/ equipment | Examined material | Degrees of freedom ¹ |
|-----------------------------------|---|-----------------------------|---|--|---------------------------------------|
| 802 – Medical Microbiology | | | | | |
| 1. | Detection of nucleic acids of infectious agents | Quantitative Real-Time PCR | SOPA-GL-01, version 08; SOPP-GL-18, version 07; SOPP-GL-54, version 04; SOPP-GL-58, version 07; SOPP-GL-59, version 07; SOPP-GL-60, version 07; SOPP-GL-74, version 01; GeneXpert II; Rotor-Gene Q MD | Plasma, blood, bone marrow, cerebrospinal fluid, urine | A, B, C, D |

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| 816 – Medical Genetics Laboratory | | | | | |
| 1. | Examination of germline genome variants | Sanger sequencing | SOPA-GL-02, version 06; SOPP-GL-01, version 06; SOPP-GL-02, version 06; SOPP-GL-03, version 06; SOPP-GL-04, version 06; SOPP-GL-05, version 06; SOPP-GL-06, version 06; SOPP-GL-28, version 06; SOPP-GL-32, version 05; SOPP-GL-33, version 06; SOPP-GL-36, version 06; SOPP-GL-37, version 06; SOPP-GL-39, version 06; SOPP-GL-41, version 06; SOPP-GL-43, version 06; SOPP-GL-44, version 05; SOPP-GL-49, version 06; SOPP-GL-57, version 05; SOPP-GL-61, version 05; ABI 3130 | Biological material containing human nucleic acid | A, B, C |
| 2. | Examination of apolipoprotein B-100 | ARMS; ACRS | SOPA-GL-03, version 06; SOPP-GL-03, version 06; SOPP-GL-04, version 06; SOPP-GL-28, version 06; SOPP-GL-29, version 06; SOPP-GL-30, version 06 | Biological material containing human nucleic acid | A, B |
| 3. | Examination of apolipoprotein E | PCR and restriction analysis | SOPA-GL-04, version 06; SOPP-GL-03, version 06; SOPP-GL-04, version 06; SOPP-GL-28, version 06; SOPP-GL-31, version 06 | Biological material containing human nucleic acid | A, B |

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| 4. | Examination of germline genome variants | Real-Time PCR | SOPA-GL-05, version 06; SOPP-GL-49, version 06; SOPP-GL-53, version 05; Rotor-Gene 6000 | Biological material containing human nucleic acid | A, B, C |
| 5. | Examination of germline genome variants [#] | NGS-MPS | SOPA-GL-06, version 06; SOPP-GL-28, version 06; SOPP-GL-33, version 06; SOPP-GL-49, version 06; SOPP-GL-61, version 05; SOPP-GL-65, version 02; SOPP-GL-66, version 05; SOPP-GL-67, version 07; SOPP-GL-68, version 05; SOPP-GL-69, version 06; SOPP-GL-70, version 06; MiSeq (Illumina); DNBSEQ-G400 (MGI); AVITI24 (Element Biosciences) | Biological material containing human nucleic acid | A, B, C |

Specification of the scope of accreditation:

| Field Nr. / Ordinal Number | Detailed information on activities within the scope of accreditation |
|----------------------------|---|
| 802/1 | DNA HBV (Hepatitis B virus); DNA CMV (Cytomegalovirus); DNA EBV (Epstein-Baar virus); DNA BKV (BK virus); RNA HCV (Hepatitis C virus) |
| 816/1 | X-linked hyper IgM syndrome (X-HIGM; <i>CD40LG</i>) X-linked severe combined immunodeficiency (X-SCID; <i>IL2RG</i>) X-linked agammaglobulinemia (XLA; BTK) AR - severe combined immunodeficiency (AR-SCID; <i>RAG1</i> , <i>RAG2</i>) Omenn's syndrome (OMENN; <i>RAG1</i> , <i>RAG2</i>) Wiskott-Aldrich syndrome (WAS; <i>WAS</i>) Chronic granulomatous disease (CGD; <i>CYBB</i>) X-linked lymphoproliferative syndrome (XLP; <i>SH2D1A</i> , <i>XIAP</i>) Autoimmune lymphoproliferative syndrome type V (ALPS V; <i>CTLA4</i>) |

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| | Dysbetalipoproteinaemia (HLP III; <i>APOE</i>) |
| 816/2 | Variant NM_000384.3:c.10580G>A; p.Arg3527Gln in gene <i>APOB</i> |
| 816/3 | Alleles E2, E3, E4 of gene <i>APOE</i> (NM_000041.4) |
| 816/4 | Factor V (NM_000130.4:1601G>A; p.(Arg534Gln), formerly G1691A-Leiden) Prothrombin (NM_000506.5:c.*97G>A, formerly G20210A) |
| 816/5 | <p><u>NGS panel Familiární hypercholesterolémie (FH)</u></p> <p><u>NGS panel HAE s normálním C1 inh</u></p> <p><u>NGS panel Hereditární periodické horečky (HRF)</u></p> <p><u>NGS panel Klinický exom</u></p> <p><u>NGS panel Primární imunodeficience – komplet (PID = IEI)</u></p> <p><u>NGS panel SCID screening</u></p> <p>A complete list of genes examined in individual panels is available on the SLG website (Society of Medical Genetics and Genomics): https://slg.cz/pracoviste/mg/32/</p> |

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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.

NGS-MPS sequencing is performed as an external service provided by another legal entity.

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|---------------|--|
| ARMS | Amplification Refractory Mutation System |
| ACRS | Amplification Created Restriction Site |
| FH | Familial hypercholesterolemia |
| NGS-MPS | Massively Parallel Sequencing |
| PCR | Polymerase Chain Reaction |
| PID | Primary immunodeficiency |
| Real-Time PCR | Polymerase Chain Reaction in Real Time |