



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.: 616/2023

Field of Accreditation: Medical Laboratory - ČSN EN ISO 15189:2013

Updated: 02.10.2024

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 | Real-Time PCR | SOPA-GL-01, version 06; SOPP-GL-18, version 07; SOPP-GL-56, version 05; SOPP-GL-58, version 07; SOPP-GL-59, version 07; SOPP-GL-60, version 07; GeneXpert; RotorGene | 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 05; SOPP-GL-02, version 05; SOPP-GL-04, version 05; SOPP-GL-05, version 05; SOPP-GL-06, version 05; SOPP-GL-28, version 06; SOPP-GL-32, version 04; SOPP-GL-33, version 03; SOPP-GL-36, version 05; SOPP-GL-37, version 05; SOPP-GL-39, version 05; SOPP-GL-41, version 05; SOPP-GL-43, version 05; SOPP-GL-44, version 05; SOPP-GL-49, version 05; SOPP-GL-56, version 05; SOPP-GL-57, version 03; SOPP-GL-61, version 03; ABI 3130 | Blood, bone marrow, paraffin block, smear from buccal mucosa | A, B, C, D |
| 2. | Examination of apolipoprotein B-100 | ARMS; ACRS | SOPA-GL-03, version 05; SOPP-GL-28, version 05; SOPP-GL-29, version 05; SOPP-GL-30, version 05 | Blood | A, B, D |
| 3. | Examination of apolipoprotein E | PCR and restriction analysis | SOPA-GL-04, version 05; SOPP-GL-04, version 05; SOPP-GL-28, version 05; SOPP-GL-31, version 05 | Blood | A, B, D |
| 4. | Examination of germline genome variants | Real-Time PCR | SOPA-GL-05, version 05; SOPP-GL-49, version 05; SOPP-GL-53, version 04; | Blood, smear from buccal mucosa | A, B, C, D |

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| | | | SOPP-GL-56, version 05; RotorGene | | |
| 5. | Examination of germline genome variants | NGS-MPS | SOPA-GL-06, version 06; SOPP-GL-28, version 05; SOPP-GL-33, version 04; SOPP-GL-49, version 05; SOPP-GL-56, version 05; SOPP-GL-61, version 04; SOPP-GL-65, version 02; SOPP-GL-66, version 04; SOPP-GL-67, version 06; SOPP-GL-68, version 05; SOPP-GL-69, version 06; SOPP-GL-70, version 05; NextSeq; MiSeq; DNBSEQ-G99 | Blood, bone marrow, paraffin block, smear from buccal mucosa | A, B, C, D |

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-Barr 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; <i>BTK</i>) AR - severe combined immunodeficiency (AR-SCID; <i>RAG1, RAG2</i>) Omenn's syndrome (OMENN; <i>RAG1, RAG2</i>) Wiskott-Aldrich syndrome (WAS; <i>WAS</i>) Chronic granulomatous disease (CGD; <i>CYBB</i>) X-linked lymphoproliferative syndrome (XLP; <i>SH2D1A, 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 p.Arg3527Gln |
| 816/3 | Alleles E2, E3, E4 |
| 816/4 | Factor V (G1691A-Leiden); Prothrombin (G20210A)] |
| 816/5 | Panel IEI: <i>ADA, AICDA, AIRE, AK2, AP3B1, ATM, BLM, BTK, CASP8, CASP10, CD19, CD27, CD8A, CD3D, CD3E, CD3G, CD40, CD59, CD247, CD40LG, CECR1, CIITA, CR2, CYBA, CYBB, DCLRE1C, DKC1, DNMT3B, DOCK8, ELANE, FERMT3, FOXP3, G6PC3, GATA2, HAX1, IFNGR1, IFNGR2, IGHM, IGLL1, IL12RB1, IL2RA, IL2RG, IL7R, ITGB2, ITK, JAK3, LCK, LIG1, LIG4, LYST, MASP2, MEFV, MVK, NBN, NBS1, NCF2, NFKB1, NFKB2, NFKBIA, NHEJ1, NLRP3, NOD2, ORAI1, PIK3CD, PIK3R1, PLG, PNP, PRF1, PRKDC, PTPRC, RAB27A, RAG1, RAG2, RFX5, RFXANK, RFXAP, RMRP, SBDS, SERPING1, SH2D1A, SLC37A4, SMARCAL1, STAT1, STAT3, STIM1, TAP1, TAP2, TAPBP, TBX1, TNFRSF13B, TNFRSF1A, TNFSF5, TREX1, TYK2, WAS, XIAP, ZAP70</i> Panel FH: <i>ABCG5, ABCG8, APOB, APOE, LDLR, LDLRAP1, LIPA, PCSK9</i> |

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

If no degree of freedom is specified, the laboratory cannot apply a flexible approach to the scope of accreditation for this examination.

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| ARMS | Amplification Refractory Mutation System |
| ACRS | Amplification Created Restriction Site |
| FH | Familial hypercholesterolemia |
| IEI | Inborn errors of immunity |
| NGS-MPS | Next Generation Sequencing – Massively Parallel Sequencing |
| PCR | Polymerase Chain Reaction |
| Real-Time PCR | Polymerase Chain Reaction in real time |