

## List of activities within the flexible scope of accreditation

**Accredited Body:** Centrum kardiovaskulární a transplantační chirurgie Brno

**CAB Name:** Genetics Laboratory

**CAB Number:** 8257

**Certificate of Accreditation No.:** 66/2025

**Field of Accreditation:** Medical Laboratory - ČSN EN ISO 15189 ed. 3:2023

**Updated:** 14. 2. 2025

### 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.	Detection of nucleic acids of infectious agents	Real-Time PCR	SOPA-GL-01, version 06; SOPP-GL-18, version 07; SOPP-GL-54, version 03; SOPP-GL-56, version 05; SOPP-GL-58, version 07; SOPP-GL-59, version 07; SOPP-GL-60, version 07; GeneXpert II	Plasma, blood, bone marrow, cerebrospinal fluid, urine	A, B, C, D

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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>816 – Medical Genetics Laboratory</b>					
1.	Examination of germline genome variants	Sanger sequencing	SOPA-GL-02, version 05; SOPP-GL-01, version 05; SOPP-GL-02, version 06; SOPP-GL-03, 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 04; 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 04; 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-03, version 05; SOPP-GL-04, version 05; SOPP-GL-28, version 06; 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-03, version 05; SOPP-GL-04, version 05; SOPP-GL-28, version 06;	Blood	A, B, D

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			SOPP-GL-31, version 05		
4.	Examination of germline genome variants	Real-Time PCR	SOPA-GL-05, version 05; SOPP-GL-49, version 05; SOPP-GL-53, version 04; SOPP-GL-56, version 05	Blood, smear from buccal mucosa	A, B, C, D
5.	Examination of germline genome variants	NGS-MPS	SOPA-GL-06, version 06; SOPP-GL-28, version 06; 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 (Illumina); MiSeq (Illumina); DNBSEQ-G99 (MGI)	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; BTK) AR - severe combined immunodeficiency (AR-SCID; <i>RAG1</i> , <i>RAG2</i> ) Omenn's syndrome (OMENN; <i>RAG1</i> , <i>RAG2</i> )

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	<p>Wiskott-Aldrich syndrome (WAS; <i>WAS</i>)</p> <p>Chronic granulomatous disease (CGD; <i>CYBB</i>)</p> <p>X-linked lymphoproliferative syndrome (XLP; <i>SH2D1A</i>, <i>XIAP</i>)</p> <p>Autoimmune lymphoproliferative syndrome type V (ALPS V; <i>CTLA4</i>)</p> <p>Dysbetalipoproteinaemia (HLP III; <i>APOE</i>)</p>
816/2	Variant p.Arg3527Gln
816/3	Alleles E2, E3, E4
816/4	<p>Factor V (G1691A-Leiden);</p> <p>Prothrombin (G20210A)]</p>
816/5	<p>Panel IIE: <i>ADA</i>, <i>AICDA</i>, <i>AIRE</i>, <i>AK2</i>, <i>AP3B1</i>, <i>ATM</i>, <i>BLM</i>, <i>BTK</i>, <i>CASP8</i>, <i>CASP10</i>, <i>CD19</i>, <i>CD27</i>, <i>CD8A</i>, <i>CD3D</i>, <i>CD3E</i>, <i>CD3G</i>, <i>CD40</i>, <i>CD59</i>, <i>CD247</i>, <i>CD40LG</i>, <i>CECR1</i>, <i>CIITA</i>, <i>CR2</i>, <i>CYBA</i>, <i>CYBB</i>, <i>DCLRE1C</i>, <i>DKC1</i>, <i>DNMT3B</i>, <i>DOCK8</i>, <i>ELANE</i>, <i>FERMT3</i>, <i>FOXP3</i>, <i>G6PC3</i>, <i>GATA2</i>, <i>HAX1</i>, <i>IFNGR1</i>, <i>IFNGR2</i>, <i>IGHM</i>, <i>IGLL1</i>, <i>IL12RB1</i>, <i>IL2RA</i>, <i>IL2RG</i>, <i>IL7R</i>, <i>ITGB2</i>, <i>ITK</i>, <i>JAK3</i>, <i>LCK</i>, <i>LIG1</i>, <i>LIG4</i>, <i>LYST</i>, <i>MASP2</i>, <i>MEFV</i>, <i>MVK</i>, <i>NBN</i>, <i>NBS1</i>, <i>NCF2</i>, <i>NFKB1</i>, <i>NFKB2</i>, <i>NFKBIA</i>, <i>NHEJ1</i>, <i>NLRP3</i>, <i>NOD2</i>, <i>ORAI1</i>, <i>PIK3CD</i>, <i>PIK3R1</i>, <i>PLG</i>, <i>PNP</i>, <i>PRF1</i>, <i>PRKDC</i>, <i>PTPRC</i>, <i>RAB27A</i>, <i>RAG1</i>, <i>RAG2</i>, <i>RFX5</i>, <i>RFXANK</i>, <i>RFXAP</i>, <i>RMRP</i>, <i>SBDS</i>, <i>SERPING1</i>, <i>SH2D1A</i>, <i>SLC37A4</i>, <i>SMARCA1</i>, <i>STAT1</i>, <i>STAT3</i>, <i>STIM1</i>, <i>TAP1</i>, <i>TAP2</i>, <i>TAPBP</i>, <i>TBX1</i>, <i>TNFRSF13B</i>, <i>TNFRSF1A</i>, <i>TNFSF5</i>, <i>TREX1</i>, <i>TYK2</i>, <i>WAS</i>, <i>XIAP</i>, <i>ZAP70</i></p> <p>Panel FH: <i>ABCG5</i>, <i>ABCG8</i>, <i>APOB</i>, <i>APOE</i>, <i>LDLR</i>, <i>LDLRAP1</i>, <i>LIPA</i>, <i>PCSK9</i></p>

### Explanatory notes:

<sup>1</sup> 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.

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