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.: 180/2026

Field of Accreditation: Medical Laboratories – ČSN EN ISO 15189 ed. 3:2023

Updated: 30. 10. 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 09; SOPP-GL-18, version 08; SOPP-GL-54, version 05; SOPP-GL-58, version 08; SOPP-GL-59, version 08; SOPP-GL-60, version 08; SOPP-GL-74, version 02; GeneXpert II; Rotor-Gene Q MD	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[1]
816 – Medical Genetics Laboratory					
1.	Examination of germline genome variants	Sanger sequencing	SOPA-GL-02, version 07; SOPP-GL-01, version 07; SOPP-GL-02, version 06; SOPP-GL-03, version 06; SOPP-GL-04, version 07; SOPP-GL-05, version 06; SOPP-GL-06, version 06; SOPP-GL-28, version 07; SOPP-GL-32, version 05; SOPP-GL-33, version 06; SOPP-GL-36, version 07; SOPP-GL-37, version 07; SOPP-GL-39, version 07; SOPP-GL-41, version 07; SOPP-GL-43, version 07; SOPP-GL-44, version 05; SOPP-GL-49, version 07; SOPP-GL-57, version 06; SOPP-GL-61, version 06; SOPP-GL-74, version 02; ABI 3130	Biological material containing human nucleic acid	A, B, C
2.	Examination of apolipoprotein B-100	ARMS; ACRS	SOPA-GL-03, version 07; SOPP-GL-03, version 06; SOPP-GL-04, version 06; SOPP-GL-28, version 07; SOPP-GL-29, version 07; SOPP-GL-30, version 07	Biological material containing human nucleic acid	A, B
3.	Examination of apolipoprotein E	PCR and restriction analysis	SOPA-GL-04, version 07; SOPP-GL-03, version 06; SOPP-GL-04, version 06; SOPP-GL-28, version 07; SOPP-GL-31, version 07	Biological material containing human nucleic acid	A, B

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Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of method procedure/ equipment	Examined material	Degrees of freedom[1]
4.	Examination of germline genome variants	Real-Time PCR	SOPA-GL-05, version 07; SOPP-GL-49, version 07; SOPP-GL-53, version 06; SOPP-GL-74, verze 02; Rotor-Gene 6000	Biological material containing human nucleic acid	A, B, C
5.	Examination of germline genome variants #	NGS-MPS	SOPA-GL-06, version 07; SOPP-GL-28, version 07; SOPP-GL-33, version 06; SOPP-GL-49, version 07; SOPP-GL-61, version 06; SOPP-GL-65, version 02; SOPP-GL-66, version 05; SOPP-GL-67, version 08; SOPP-GL-68, version 06; SOPP-GL-69, version 06; SOPP-GL-70, version 06; SOPP-GL-74, verze 02; 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; *CD40LG*) X-linked severe combined immunodeficiency (X-SCID; *IL2RG*) X-linked agammaglobulinemia (XLA; BTK) AR - severe combined immunodeficiency (AR-SCID; *RAG1*, *RAG2)* Omenn's syndrome (OMENN; *RAG1*, *RAG2*) Wiskott-Aldrich syndrome (WAS; *WAS*) Chronic granulomatous disease (CGD; *CYBB*)

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Field Nr. / Ordinal Number	Detailed information on activities within the scope of accreditation
	X-linked lymphoproliferative syndrome (XLP; *SH2D1A*, *XIAP*) Autoimmune lymphoproliferative syndrome type V (ALPS V; *CTLA4*) Dysbetalipoproteinaemia (HLP III; *APOE*)
816/2	Variant NM_000384.3:c.10580G>A; p.Arg3527Gln in gene *APOB*
816/3	Alleles E2, E3, E4 of gene *APOE* (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	NGS panel Familiární hypercholesterolémie (FH) NGS panel HAE s normálním C1 inh NGS panel Hereditární periodické horečky (HRF) NGS panel Klinický exom NGS panel Primární imunodeficience – komplet (PID = IEI) NGS panel SCID screening 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/

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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.

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