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.: 616/2023

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

Updated: 06.09.2024

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

List of activities within the flexible scope of accreditation

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 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 05; 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

List of activities within the flexible scope of accreditation

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of method procedure/ equipment	Examined material	Degrees of freedom[1]
			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; *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*) X-linked lymphoproliferative syndrome (XLP; *SH2D1A, XIAP*) Autoimmune lymphoproliferative syndrome type V (ALPS V; *CTLA4*)

List of activities within the flexible scope of accreditation

	Dysbetalipoproteinaemia (HLP III; *APOE*)
816/2	Variant p.Arg3527Gln
816/3	Alleles E2, E3, E4
816/4	Factor V (G1691A-Leiden); Prothrombin (G20210A)]
816/5	Panel IEI: *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* Panel FH: *ABCG5, ABCG8, APOB, APOE, LDLR, LDLRAP1, LIPA, PCSK9*

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.

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