List of activities within the flexible scope of accreditation

Accredited Body: GENNET, s.r.o.
CAB Name: Laboratoře GENNET
CAB Number: 8068
Certificate of Accreditation No.: 374/2023
Field of Accreditation: Medical laboratory - ČSN EN ISO 15189:2013
Updated: 17.06.2024

1. **Molecular Genetics Laboratory** Pekařská 635/6, 158 00 Praha 5

Examinations:

Ordinal number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/ equipment	Examined material	Degrees of freedom[1]
816 – Medical Genetics Laboratory					
1.	Examination of germline genomic variants	Real-Time PCR	SOP-MGL-002 V10; SOP-MGL-021 V4; SOP-MGL-022 V3; SOP-MGL-023 V3; SOP-MGL-037 V1	Amniotic fluid, peripheral blood, buccal smear	A, B, C, D
2.	Examination of germline genomic variants	PCR followed by fragment analysis	SOP-MGL-017 V4; SOP-MGL-004 V8; SOP-MGL-011 V6; SOP-MGL-024 V3; SOP-MGL-001 V8; SOP-MGL-010 V6; ABI PRISM 3130; 3130XL	Amniotic fluid, peripheral blood, chorionic villi, fetus tissue	A, B, C, D
3.	Examination of germline genomic variants	PCR followed by sequencing analysis	SOP-MGL-009 V8; ABI PRISM 3130; 3130XL	Amniotic fluid, peripheral blood, chorionic villi,	A, B, C, D

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Ordinal number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/ equipment	Examined material	Degrees of freedom[1]
4.	Examination of germline genomic variants	NGS	SOP-MGL-013 V8; PP-MGL-009 V2; PP-MGL-010 V2; PP-MGL-011 V1; PP-MGL-028 V3; PP-MGL-029 V3; PP-MGL-030 V5; PP-MGL-039 V2 PP-MGL-038 V2; PP-MGL-045 V2; PP-MGL-046 V1; PP-MGL-055 V1 PP-MGL-056 V1 NextSeq; NextSeq Dx; NovaSeq X Plus; Illumina platform	Peripheral blood,	A, B, C, D
5.	Non-invasive prenatal test of chromosomal aneuploidies (NIPT)	NGS	SOP-MGL-038 V1; PP-MGL-031 V1; PP-MGL-036 V2; NextSeq; NextSeq Dx; Illumina platform	Peripheral blood	A, B, C

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Field Nr. / Ordinal number	Detailed information on activities within the scope of accreditation
816/1	Genes analyzed for germline variants: *Factor V (G1691A, Factor II (G20210A), MTHFR (C677T, A1298C), PAI-1 (4G/5G), GJB2 (35delG;)* Determination of alleles/allelic groups for celiac disease: *DQA1*02, *03, *05, DQB1*02, DQB1*03:02;* Determination of HLA traits B*27for Morbus Bechterev
816/2	Germline variants analyzed within the CFTR gene: *S549N, S549R, R553X, G551D, V520F, delI507, delF508, 1717-1G→A, G542X, R560T, 3120+1G→A, A455E, R117H, 394delTT, 2184delA, 2789+5G→A, 1898+1G→A, 621+1G→T, 711+1G→T, G85E, R347P, R347H, W1282X, R334W, 1078delT, 3849+10kbC→T, R1162X, N1303K, 3659delC, 3905insT, CFTRdele2,3(21kb), polymorphism 5/7/9 T in intron 8, 3876delA a 2183AA→G.* Elucigene CF-EU2v2 examine also these mutations*: E60X, P67L, 444delA, R117C, Y122X, L206W, 1811+1,6kbA→G, 2143delT, 2347delG, W846X, Q890X, 3272-26A→G, R1066C, Y1092X(C→A), M1101K, D1152H, 1677delTA, R1158X, S1251N;* Microdeletions in the AZF areas (azoospermic factors) of the chromosome Y*: (AZFa, AZFb, AZFc);* Investigated germline variants in genes*: BRCA2, BRCA1, CHEK2, MLH1, MSH2, VHL, SMN1, SMN2, MEN1, DMD1, DMD2, ATM, APC, NF1, NF2, APC, TSC2, TP53, SMA, CDH1, STK11, TSC1, HSP,PTEN, FLCN, SMARCB1, PALB2, PMS2, MSH6-MUTYH, STRC, CATSPER2, OTOA, RAD51D, RAD51C, RAD50, MECP2;* Examination of the *FMR1* gene*:* expansion of CGG trinucleotides*;* Analysis of these chromosomal aneuploidies: 2, 4, 6, 7, 13, 14, 15, 16, 18, 21, 22, X, Y.
816/3	Mutations in the *GJB2* gene
816/4	NGS panel CZECANCA used for the analysis of these genes: *AIP; ALK; APC; ATM; BAP1; BARD1; BLM; BMPR1A; BRCA1; BRCA2; BRIP1;BUB1B; CDC73; CDH1; CDK4; CDKN2A; CDKN2A; CDKN1C; CEBPA; CHEK2; DICER1; DPYD; DIS3L2;EPCAM; EXT1; EXT2; EZH2; FANCA; FANCB; FANCC; FANCD2; FANCE; FANCF; FANCG; FANCI; FANCL; FANCM; FBXW7; FH; FLCN; GATA2; GPC3; HRAS; KCNQ1OT1; KIT; LIG4; MAX; MEN1; MET; MLH1; MLH3; MRE11A; MSH2; MSH6; MUTYH; NBN; NF1; NF2;NSD1; PALB2; PAX6; PHOX2B; PINK1; PMS2; PTPN11; POLD1; POLE; PRKAR1A; PTCH1; PTEN; RAD50; RAD51; RAD51C; RAD51D; RB1; RECQL; RECQL4; RET; RUNX1; SDHB; SDHAF; SMAD4; SMARCA4; SMARCB1; STK11; SUFU; TERT; TMEM127; TP53; TSC1; TSC2; VHL; WT1; DIS3L2; PMS2; SBDS; SDHAF2; SDHA; SDHC; SDHD; SLX4; AIP; ALK; BUB1B; CDC73; CDKN1C; CEBPA; EZH2; FBXW7; GPC3; HRAS; KCNQ1OT1; LIG4; MAX; NSD1; PAX6; PHOX2B; PINK1; PTPN11; PHOX2B; RECQL4; RUNX1; SDHA; SDHAF; SDHAF2; SDHC; SETBP1; SLX4; SMARCE1; WAS* NGS panel CARRIER TEST used for the analysis of these genes: *ABCA4; ACADM; ACADS; ACADVL; ADGRV1; AGL; ALPL; ANXA5; AR; ARSA; ASL; ASPA; ASS1; ATM; ATP7B; BCHE; BLM; BTD; CBS; CDH23; CFTR; CHRNE; CLRN1; COL4A5; CTNS; CYP21A2; CYP27A1; DHCR7; DMD; F2; F5; FAH; FSHR; G6PC; GALT; GBA; GCDH; GJB2; GLA; GLB1; GNPTAB; HADHA; HBB; HEXA; HFE; IDUA; IKBKAP; IL2RG; MCCC1; MCCC2; MEFV; MTHFR; MTM1; MYO7A; NBN; NPC1; NPC2; OTC; PAH; PCDH15; PEX1; PEX10; PEX12; PEX13; PEX14; PEX16; PEX2; PEX6; PEX7; PMM2; SERPINA1; SGSH; SLC26A4; SMN1; SMPD1; TGM1; TPP1; USH1C; USH2A*; Microdeletions of Y chromosome analyzed using these markers: *sY14(SRY), sY86 + sY84(AZFa), sY127 + sY134(AZFb), sY254 + sY255(AZFc)* *NGS panel* EXOM: The complete list of examined genes is available on the webpages of the Society for medical genetics and genomics here: https://slg.cz/pracoviste/mg/61/
816/5	NGS Non-Invasive Prenatal Test method analyses the aneuploidy state of the chromosomes 13,18 21, X, Y.

List of activities within the flexible scope of accreditation

2. Cytogenetics Laboratory – Pekařská Pekařská 635/6, 158 00 Praha 5

Examinations:

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/ equipment	Examined material	Degrees of freedom[1]
816 – Medical Genetics Laboratory					
1.	Examination of constitutional karyotype	Cytogenetic analysis of G-banded slides	SOP-CL-001 V10; SOP-CL-002 V5; SOP-CL-003 V5; SOP-CL-004 V5; PP-CL-002 V1; Metaphase finder (Applied Spectral Imaging)	Peripheral blood, umbilical blood, amniotic fluid, chorionic villi	A, B
2.	Examination of chromosomal aberrations	FISH	SOP-CL-009 V5; Fluorescence microscope using digital image analysis (LUCIA)	Peripheral blood, umbilical blood, amniotic fluid, chorionic villi	A, B
3.	Examination of unbalanced chromosomal aberrations and germinal genome	SNP array	SOP-CL-016 V5; PP-CL-004 V1; iScan Illumina	Biological material containing genomic DNA	A, B

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3. PGT Laboratory Pekařská 635/6, 158 00 Praha 5

Examinations:

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/ equipment	Examined material	Degrees of freedom[1]
816 – Medical Genetics Laboratory					
1.	Preimplantation genetic testing of monogenic diseases and aneuploidies	Karyomapping	SOP-PGTL-002 V5; iScan Illumina	Trophectoderm Blastomere	A, B, C, D
2.	Preimplantation genetic testing of aneuploidies	NGS	SOP-PGTL-004 V4; NextSeq; NextSeq Dx; Illumina platform	Trophectoderm Blastomere	A, B, C, D

Specification of the scope of accreditation:

Field Nr. / Ordinal Number	Detailed information on activities within the scope of accreditation
816/1	Screening of aneuploidies and structural aberrations, screening of aneuploidies and monogenic diseases
816/2	Screening of aneuploidies, screening of aneuploidies and structural aberrations

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4. Cytogenetics Laboratory – Liberec Liliová 118/1, 460 01 Liberec

Examinations:

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/ equipment	Examined material	Degrees of freedom[1]
816 – Medical Genetics Laboratory					
1.	Examination of constitutional karyotype	Cytogenetic analysis of G-banded slides	SOP-CL-001 V10; SOP-CL-002 V5; PP-CL-002 V1; Metaphase Finder and Automated Karyotyping System (Applied Spectral Imaging)	Peripheral blood, umbilical blood, amniotic fluid, chorionic villi	A, B

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5. IVF Laboratory – Liberec Liliová 118/1, 460 01 Liberec

Examinations:

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/ equipment	Examined material	Degrees of freedom[1]
Laboratory examinations for IVF					
1.	Evaluation of ejaculate	Microscopic; Macroscopic	SOP-IVF-001 V15; PP-IVF-004 V4	Human semen - ejaculate	A, B

6. IVF Laboratory – Letná Kostelní 292/9, 170 00 Praha 7

Examinations:

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/ equipment	Examined material	Degrees of freedom[1]
Laboratory examinations for IVF					
1.	Evaluation of ejaculate	Microscopic; Macroscopic	SOP-IVF-001 V15; PP-IVF-004 V4	Human semen - ejaculate	A, B

7. IVF Laboratory – Archa Na Poříčí 1046/24, 110 00 Praha 1

Examinations:

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/ equipment	Examined material	Degrees of freedom[1]
Laboratory examinations for IVF					
1.	Evaluation of ejaculate	Microscopic; Macroscopic	SOP-IVF-001 V15; PP-IVF-004 V4	Human semen - ejaculate	A, B

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8. Immunology Laboratory

Examinations:

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/ equipment	Examined material	Degrees of freedom[1]
813 - Allergology and Immunology Laboratory					
1.	Immunoglobulins	Immunoturbidimetry	SOP-IML-101 V8; PPT-IML-009 V4 OptiLite	Serum, plasma	A, B, C
2.	Specific Proteins	Immunoturbidimetry	SOP-IML-102 V8; PPT-IML-009 V4 OptiLite	Serum, plasma	A, B, C
3.	Autoantibodies	Immunoassay with fluorimetric detection	SOP-IML-051 V6; Phadia 250	Serum, plasma	A, B, C
4.	Autoantibodies	Indirect immunofluorescence	SOP-IML-201 V5; QuantaLyser Eurostar III Plus	Serum, plasma	A, B, C
5.	Specific IgE	Immunoassay with fluorimetric detection	SOP-IML-402 V9; Phadia 250	Serum, plasma	A, B, C
6.	Immunophenotyping of cell subpopulations	Flow cytometry	SOP-IML-301 V6; Navios	Blood	A, B, C
7.	Anti-Müllerian hormone (AMH)	Immunoassay with luminometric detection	SOP-IML-151 V1; Access 2	Serum, plasma	A

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Specification of the scope of accreditation:

Field Nr. / Ordinal Number	Detailed information on activities within the scope of accreditation
813/1	IgA, IgG, IgM
813/2	C-reactive protein (CRP)
813/3	Anti-tissue transglutaminase IgA
813/4	ANA IgG (IF), ANA titer, ANA nuclear pattern, ANA cytoplasmic pattern
813/5	sIgE - allergen (code CAP)
813/6	T lymphocyte CD3+, Th lymphocyte CD3+CD4+, Tc lymphocyte CD3+CD8+, B lymphocyte CD19+, NK lymphocyte CD3-CD16+56+

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.

PCR	*Polymerase Chain Reaction*
Real-Time PCR	*Real–Time Polymerase Chain Reaction*
NGS	*Next Generation Sequencing, also known as massively parallel sequencing*
FISH	*Fluorescent In Situ Hybridization*
SNP Array	*Whole genome screening utilizing the known single-nucleotide-polymorphism*