# 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.**: 534/2024
**Field of Accreditation**: Medical laboratory - ČSN EN ISO 15189 ed. 2:2013
**Updated**: 21.07.2025

**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;<br>SOP-MGL-021 V4;<br>SOP-MGL-022 V3;<br>SOP-MGL-023 V3;<br>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 V6;<br>SOP-MGL-004 V9;<br>SOP-MGL-011 V8;<br>SOP-MGL-024 V5;<br>SOP-MGL-001 V9;<br>SOP-MGL-010 V8;<br>PP-MGL-058 V1;<br>PP-MGL-059 V1;<br>PP-MGL-061 V1;<br>PP-MGL-062 V1;<br>PP-MGL-063 V1;<br>PP-MGL-065 V1;<br>PP-MGL-066 V1;<br>PP-MGL-068 V1;<br>ABI PRISM 3130; 3130XL<br>ABI 3500Dx<br>SeqStudioFlex, Applied Biosystems | Amniotic fluid, peripheral blood, chorionic villi, fetus tissue | 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] |
|---|---|---|---|---|---|
| 3. | Examination of germline genomic variants | PCR followed by sequencing analysis | SOP-MGL-009 V10;<br>PP-MGL-060 V1;<br>ABI PRISM 3130; 3130XL, ABI 3500Dx<br>SeqStudioFlex, Applied Biosystems | Amniotic fluid, peripheral blood, chorionic villi | A, B, C, D |
| 4. | Examination of germline genomic variants | NGS | SOP-MGL-013 V8;<br>PP-MGL-009 V2;<br>PP-MGL-010 V2;<br>PP-MGL-011 V1;<br>PP-MGL-028 V3;<br>PP-MGL-029 V3;<br>PP-MGL-030 V5;<br>PP-MGL-038 V2;<br>PP-MGL-039 V2;<br>PP-MGL-045 V2;<br>PP-MGL-046 V1;<br>PP-MGL-055 V1;<br>PP-MGL-056 V1;<br>NextSeq; NextSeq Dx; NovaSeq X Plus; platforma Illumina | Peripheral blood | A, B, C, D |
| 5. | Non-invasive prenatal test of chromosomal aneuploidies (NIPT) | NGS | SOP-MGL-038 V1;<br>PP-MGL-031 V1;<br>PP-MGL-036 V2;<br>NextSeq; NextSeq Dx; platforma Illumina | Peripheral blood | A, B, C |

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| 816/1 | Genes analyzed for germline variants: *Factor V (G1691A, Factor II (G20210A), MTHFR (C677T, A1298C), PAI-1 (4G/5G), GJB2 (35delG;)*<br>Determination of alleles/allelic groups for celiac disease: *DQA1*02, *03, *05, DQB1*02, DQB1*03:02;*<br>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;*<br>Microdeletions in the AZF areas (azoospermic factors) of the chromosome Y*: (AZFa, AZFb, AZFc);*<br>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;*<br>Examination of the *FMR1* gene*:* expansion of CGG trinucleotides*;*<br>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:<br>*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*<br>NGS panel CARRIER TEST used for the analysis of these genes:<br>*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)*<br>*NGS panel* EXOM:<br>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 | Conventional cytogenetic analysis | SOP-CL-002 V1;<br>PP-CL-001 V1;<br>PP-CL-002 V3;<br>PP-CL-004 V1;<br>PP-CL-005 V1;<br>PP-CL-006 V1;<br>PP-CL-007 V1;<br>PP-CL-008 V1;<br>PP-CL-009 V1;<br>PP-CL-010 V1;<br>PP-CL-011 V1;<br>PP-CL-012 V1;<br>PP-CL-013 V1;<br>PP-CL-014 V1;<br>PP-CL-015 V1;<br>PP-CL-016 V1;<br>PP-CL-017 V1; | Peripheral blood, umbilical blood, amniotic fluid, chorionic villi | A, B |
| 2. | Examination of chromosomal aberrations | FISH | SOP-CL-003 V1;<br>PP-CL-001 V1;<br>PP-CL-018 V1; | Peripheral blood, umbilical blood, amniotic fluid, chorionic villi | A, B |
| 3. | Examination of unbalanced chromosomal aberrations and germinal genome | SNP array | SOP-PGTL/CL-001 V1;<br>PP-PGTL/CL-001 V6;<br>PP-CL-001 V1;<br>PP-CL-019 V1;<br>PP-CL-020 V1;<br>PP-CL-021 V1;<br>PP-CL-022 V1;<br>PP-CL-023 V1;<br>iScan Illumina<br>Infinium Global Scrreening Array-24+v3.0 Kit_CYTO | Biological material containing genomic DNA | A, B |

# List of activities within the flexible scope of accreditation

**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 | SNP array | SOP-PGTL/CL-001 V1;<br>PP-PGTL/CL-001 V6;<br>PP-PGTL-001 V1<br>iScan Illumina<br>Infinium Global Screening Array-24+v3.0 Kit_DTC | Trophectoderm | A, B, C, D |
| 2. | Preimplantation genetic testing of aneuploidies | NGS | SOP-PGTL-001 V5;<br>PP-PGTL-001 V1;<br>PP-PGTL-006 V3;<br>PP-PGTL-022 V4;<br>PP-PGTL-021 V1;<br>PP-PGTL-020 V1;<br>NextSeq; NextSeq Dx; Illumina platform | Trophectoderm | 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 | Testing of aneuploidies and structural aberrations, screening of aneuploidies and monogenic diseases |
| 816/2 | Testing of aneuploidies, screening of aneuploidies and structural aberrations |

# List of activities within the flexible scope of accreditation

**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 | Conventional cytogenetic analysis | SOP-CL-002 V1;<br>PP-CL-002 V3;<br>PP-CL-006 V1;<br>PP-CL-014 V1;<br>PP-CL-015 V1;<br>PP-CL-016 V1 | Peripheral blood, umbilical blood, amniotic fluid, chorionic villi | A, B |

**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;<br>Macroscopic | SOP-IVF-001 V15;<br>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;<br>Macroscopic | SOP-IVF-001 V15;<br>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;<br>Macroscopic | SOP-IVF-001 V15;<br>PP-IVF-004 V4 | Human semen - ejaculate | A, B |

# List of activities within the flexible scope of accreditation

## 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<br>PPT-IML-009 V4;<br>OptiLite | Serum, plasma | A, B, C |
| 2. | Specific Proteins | Immunoturbidimetry | SOP-IML-102 V8;<br>PPT-IML-009 V4<br>OptiLite | Serum, plasma | A, B, C |
| 3. | Autoantibodies | Immunoassay with fluorimetric detection | SOP-IML-051 V6;<br>PPT-IML-004 V7<br>Phadia 250 | Serum, plasma | A, B, C |
| 4. | Autoantibodies | Indirect immunofluorescence | SOP-IML-201 V6<br>QuantaLyser<br>Eurostar III Plus | Serum, plasma | A, B, C |
| 5. | Specific IgE | Immunoassay with fluorimetric detection | SOP-IML-402 V10;<br>PPT-IML-004 V7<br>Phadia 250 | Serum, plasma | A, B, C |
| 6. | Immunophenotyping of cell subpopulations | Flow cytometry | SOP-IML-301 V6;<br>PPT-IML-003 V5;<br>PPT-IML-013 V1<br>Navios; DxFLEX | Blood | A, B, C |
| 7. | Anti-Müllerian hormone (AMH) | Immunoassay with luminometric detection | SOP-IML-151 V2<br>Access 2 | Serum, plasma | A, B |

# List of activities within the flexible scope of accreditation

## 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) |
| 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* |