# List of activities within the flexible scope of accreditation

**Accredited Body**: Genetika Plzeň, s.r.o.

**CAB Name:** Genetics Laboratory

**CAB Number:** 8034

**Certificate of Accreditation No.**: 389/2025

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

**Updated**: 19.10.2026

**Examinations:**

| Ordinal Number | Analyte/ parameter/diagnostics | Principle of examination | Identification of method procedure/ equipment | Examined material | Degrees of freedom[1] |
|---|---|---|---|---|---|
| **813 - Allergology and Immunology Laboratory** | | | | | |
| 1. | Antibodies | Immunoassay with photometric detection | SOPV.GP 302, version 004;<br>SOPV.GP 303, version 005;<br>SOPV.GP 304, version 003;<br>ELISA Reader Opsys MR | Serum | A, B, C |
| 2. | Antisperm antibodies | Agglutination | SOPV.GP 305, version 003;<br>PP.GP 301, version 002 | Ejaculate, serum | A, B |
| 3. | Sperm acrosomes | Indirect immunofluorescence | SOPV.GP 306, version 001;<br>PP.GP 301, version 002 | Ejaculate | A, B |
| 4. | Anti-ovarian, anti-zonal and anti-spermatozoa antibodies | Indirect immunofluorescence | SOPV.GP 308, version 004;<br>PP.GP 302, version 001 | Serum | A, B, C |
| **816 – Medical Genetics Laboratory** | | | | | |
| 1. | Examination of unbalanced chromosomal aberrations | aCGH | SOPV.GP 101, version 007;<br>PP.GP 101, version 002;<br>PP.GP 102, version 003;<br>PP.GP 103, version 001;<br>PP.GP 702, version 002;<br>PP.GP 705, version 004;<br>SurePrint G3 Unrestricted CGH ISCA v2, 8x60K;<br>SurePrint G3 CGH+SNP, 4x180K;<br>SurePrint G3 Unrestricted CGH ISCA v2, 4x180K | Peripheral and fetal blood, buccal smear, amniotic fluid, chorionic villi and aborted tissue | A, B |

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|---|---|---|---|---|---|
| 2. | Examination of constitutional karyotype | Conventional cytogenetic analysis | SOPV.GP 102, version 003 | Peripheral and fetal blood, buccal smear, amniotic fluid, chorionic villi and aborted tissue | A, B |
| 3. | Examination of constitutional chromosomal aberrations | FISH | SOPV.GP 103, version 003;<br>PP.GP 501, version 001 | Peripheral and fetal blood, buccal smear, amniotic fluid, chorionic villi and aborted tissue, blastomere, trophectoderm | A, B |
| 4. | Preimplantation genetic testing (PGT) of germline genome | NGS | SOPV.GP 501, version 003;<br>PP.GP 507, version 003;<br>PP.GP 902, version 001;<br>Miseq platforma Illumina | Trophectoderm | A, B, D |
| 5. | Examination of germline genome variants | AS PCR | SOPV.GP 701, version 002;<br>SOPV.GP 902, version 001;<br>PP.GP 509, version 001;<br>PP.GP 702, version 002;<br>PP.GP 705, version 004;<br>PP.GP 707, version 002;<br>PP.GP 708, version 003;<br>PP.GP 714, version 002;<br>PP.GP 715, version 003;<br>PP.GP 716, version 002;<br>PP.GP 717, version 002;<br>PP.GP 719, version 001;<br>PP.GP 720, version 001 | Peripheral blood, buccal swab, amniotic fluid (native and cultured), chorionic villi (native and cultured), aborted tissue | 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] |
|---|---|---|---|---|---|
| 6. | Examination of germline genome variants | Multiplex PCR | SOPV.GP 702, version 002;<br>SOPV.GP 708, version 003;<br>PP.GP 702, version 002;<br>PP.GP 705, version 004;<br>PP.GP 707, version 002;<br>PP.GP 712, version 001;<br>PP.GP 714, version 002;<br>PP.GP 719, version 001;<br>PP.GP 722, version 002;<br>PP.GP 723, version 002 | Peripheral blood, buccal swab, amniotic fluid (native and cultured), chorionic villi (native and cultured), aborted tissue | A, B, C, D |
| 7. | Examination of germline genome variants | QF PCR | SOPV.GP 703, version 002;<br>PP.GP 702, version 002;<br>PP.GP 703, version 001;<br>PP.GP 704, version 002;<br>PP.GP 705, version 004;<br>PP.GP 707, version 002;<br>PP.GP 712, version 001;<br>PP.GP 720, version 001;<br>ABI Prism 3500 Genetic Analyzer | Peripheral blood, buccal swab, amniotic fluid (native and cultured), chorionic villi (native and cultured), aborted tissue | A, B, C |
| 8. | Examination of germline genome variants | Real-Time PCR | SOPV.GP 705, version 002;<br>PP.GP 702, version 002;<br>PP.GP 705, version 004;<br>PP.GP 707, version 002;<br>Rotor-Gene RG6000 | Peripheral blood, buccal swab | A, B |
| 9. | Examination of germline genome variants | PCR with fragment analysis | SOPV.GP 706, version 002;<br>PP.GP 702, version 002;<br>PP.GP 705, version 004;<br>PP.GP 707, version 002;<br>PP.GP 712, version 001;<br>ABI Prism 3500 Genetic Analyzer | Peripheral blood, buccal swab, amniotic fluid (native and cultured), chorionic villi (native and cultured), aborted tissue | 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] |
|---|---|---|---|---|---|
| 10. | Examination of germline genome variants | Sanger sequencing | SOPV.GP 707, version 002;<br>PP.GP 702, version 002;<br>PP.GP 705, version 004;<br>PP.GP 707, version 002;<br>PP.GP 711, version 001;<br>PP.GP 712, version 001;<br>ABI Prism 3500 Genetic Analyzer | Peripheral blood, buccal swab, amniotic fluid (native and cultured), chorionic villi (native and cultured), aborted tissue | A, B, C |
| 11. | Examination of germline genome variants | MLPA | SOPV.GP 710, version 002;<br>PP.GP 702, version 002;<br>PP.GP 705, version 004;<br>PP.GP 706, version 001;<br>PP.GP 707, version 002;<br>PP.GP 711, version 001;<br>PP.GP 712, version 001;<br>PP.GP 713, version 002;<br>PP.GP 719, version 001;<br>ABI Prism 3500 Genetic Analyzer | Peripheral blood, buccal swab, amniotic fluid (native and cultured), chorionic villi (native and cultured), aborted tissue | A, B, C |
| 12. | Examination of germline genome variants | NGS | SOPV.GP 901, version 005;<br>PP.GP 504, version 005;<br>PP.GP 505, version 004;<br>PP.GP 705, version 004;<br>PP.GP 711, version 001;<br>PP.GP 720, version 001;<br>PP.GP 724, version 002;<br>PP.GP 726, version 002;<br>PP.GP 901, version 001;<br>PP.GP 902, version 002;<br>Miseq platform Illumina;<br>DNBSEQ G99 platform MGI | Peripheral blood | A, B, C, D |
| **Laboratory examinations for IVF** | | | | | |
| 1. | Examination of spermiogram | Microscopy;<br>Macroscopy | SOPV.GP 301, version 004 | Ejaculate | 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 | antibodies against Cardiolipin in IgG and IgM classes, antibodies against Annexin V in IgG and IgM classes, antibodies against Beta2-Glycoprotein I in IgA a IgG classes, antibodies against phosphatidic acid in IgG and IgM classes, antibodies against phosphatidylethanolamine in IgG and IgM classes, antibodies against phosphatidylinositol inIgG and IgM classe, antibodies against phosphatidylserine in IgG and IgM classes |
| 813/2 | antibodies against sperms - MarTest in IgA and IgG classes |
| 813/3 | intra acrosomal enzymes |
| 813/4 | antibodies against ovaries, against zona pellucida and against sperms |
| 816/4 | PGT-A, PGT-SR (24 chromosomes) |
| 816/5 | genes: *GJB2-35delG, W24X816/2;*<br>HLA typization - alleles and allelic groups: DQ2, DQ8, HLA-B27, KIR |
| 816/6 | Microdeletion on the Y chromosome;<br>Mutation of CFTR gene: 711+ 1G>T, 2043delG, 1677delTA, W1282X, R1283M, K710X, 3849+10kbC>T, 2789+5G>A, M1101K, G85E, 3905insT, 1525-1G>A, 2184delA, 3659delC, N1303K, 2184insA, 1812-1G->A, CFTRdele2,3, 2143delT, Y569D, R1162X, A561E, S1251N, P67L, R1158X, 1609delCA, Q493X, E60X, 1898+1G>A, 1898+5G>T, I507del, F508del, V520F, 394delTT, D1152H, V232D, L218X, 621+2T>C, 1717-1G>A, L206W, E92X, 3120+1G>A, G542X, S549N, G551D, 712-1G>T, R553X, 3272-26A>G, R560T, 2183AA>G, R117H, R117C, 1811+1.6kbA>G, 2869insG, Y122X, Q890X, R1066C, R347H, R347P, 1161delC, 1154ins TC, E92K, I336K, R334W, Y1092X (C>A), 621+1G>T, 1078delT, A455E , Intron 8- 5T(TG9-13)/7T/9T |
| 816/7 | Chromosomes 13, 15, 16, 18, 21, 22, X, Y<br>STR markers: D13S634, D13S742, D13S305, D13S628, D13S800, D13S252, D13S325, D13S317, D13S1492, D18S535, D18S391, D18S386, D18S978, D18S499, D18S976, D18S1002, D18S858, GATA178F11, D18S1364, D21S1435, D21S11, D21S1270, D21S1411, D21S1444, D21S1442, D21S1437, D21S2055, D21S1409, D21S1280, D21S1446, D15S643, D15S657, D15S659, D15S822, D15S1513, D15S205, D15S1002, D15S1014, S15S1016, D15S1040, D16S539, D16S753, D16S2620, D16S3396, D22S1045, D22S683, D22S686, D22S689, GATA198B05, D14S49, D14S77, D14S43, D14S68, D14S51, P39, DXS981, DXS1187, XHPRT, DXS996, DXS1283E, DYS448, SRY, X22, AMEL, DXS2390, DXYS267, DXYS218, ZFX/Y, T1 (7q34/Xq13), T2 (Xq23/2p23.3), T3 (3p24.2/Xq21.1), sY625, DXS6809, DXS6854, DXS6803, DXS6807 |
| 816/8 | Genes: *F2* (rs1799963), *F5* (rs6025), *MTHFR* (rs1801133, rs1801131), *PAI1* (4G/5G) |
| 816/9 | Expansion CGG repetition in *FMR1* gene |
| 816/10 | Genes: *ATM, APC, BARD1, BRCA1, BRCA2, BRIP1, CDH1, CHEK2, EPCAM, MLH1, MSH2, MSH6, MUTYH, NBN, PALB2, PMS2, PTEN, RAD51C, RAD51D, STK11, TP53* |
| 816/11 | Genes: *ATM, APC, BARD1, BRCA1, BRCA2, BRIP1, CDH1, CHEK2, EPCAM, MLH1, MSH2, MSH6, MUTYH, NBN, PALB2, PMS2, PTEN, RAD51C, RAD51D, STK11, TP53* |

# List of activities within the flexible scope of accreditation

| Field Nr. / Ordinal Number | Detailed information on activities within the scope of accreditation |
|---|---|
| | Genes: *SMN1, SMN2* |
| 816/12 | Carrier screening - genes: *AR geny (88 genes): ABCA4, ABCC8, ACADM, ACADVL, AGA, AGL, AHI1, AIRE, ALDOB, ANO10, ARSA, ASPA, ASS1, ATP7B, BCKDHA, BCKDHB, CAPN3, CATSPER2, CEP290, CFTR, CLN5, CLRN1, CNGA3, CNGB3, COL7A1, CPT1A, CPT2, CYP1B1, CYP21A2, DBT, DHCR7, DLD, DYNC2H1, FAH, FKTN, G6PC, GAA, GALT, GBA, GBE1, GCDH, GJB2, GJB3, GJB6, GLB1, GLE1, GNPTAB, GRIP1, HADHA, HBA1, HBA2, HBB, HEXA, HEXB, HPS1, HPS3, CHRNE, ELP1, KCNJ11, MCOLN1, MEFV, MMUT, MTHFR, MYO7A, NAGA, NEB, NPHS1, OCA2, PAH, PCCA, PCCB, PKHD1, PMM2, POLG, PROP1, RMRP, SERPINA1, SGSH, SLC17A5, SLC26A4, SMN1, SMPD1, STRC, TMEM216, TNXB, TPP1, TYR, USH2A; X-bonded (15 genes): ABCD1, AR, DMD, F8, F9, G6PD, GLA, L1CAM, MID1, NR0B1, OTC, PLP1, RPGR, RS1, SLC6A8*<br>Reproductive disorders - genes: *ANXA5, F2, F5, FSHR, MTHFR* (only selected variants: rs112782763, rs28717001, rs28651243, rs113588187, rs1799963, rs6025, rs6166, rs1801133, rs1801131), AZFa (regions of STS markers sY83, sY1064, sY86, sY84, genes DDX3, UTY and USP9Y and the region of STS marker sY1065), control regions of STS markers sY82, sY88, sY105, AZFb (region specified by genomic coordinate: "chrY:18642658-18645962" and regions of STS markers sY121, sY127, sY134, sY143, sY1192/1191), AZFc (regions of STS markers sY1192/1191, regions specified by genomic coordinates "chrY:23210293-23210472", "chrY:23374917-23375096", „chrY:23419840-23420019", „chrY:23586751-23586930“, „chrY:23730251-23730430“, „chrY:23960929-23961108“, "chrY:24272664-24272843", "chrY:25237639-25878308", region STS marker sY14 and area "chrY:56855363-56857442").<br>Oncopanel – genes: *ATM, APC, BARD1, BRCA1, BRCA2, BRIP1, CDH1, CHEK2, EPCAM, MLH1, MSH2, MSH6, MUTYH, NBN, PALB2, PMS2, PTEN, RAD50, RAD51C, RAD51D, STK11, TP53*<br>*BAP1, BLM, BMPR1A, CDC73, CDK4, CDKN1C, CDKN2A, DICER, DIS3L2, DPYD, ERCC2, ERCC3, FANCC, FANCM, FH, FLCN, GPC3, KIT, MEN1, MET, MLH3, NF1, NF2, POLD1, POLE, PRKAR1A, PTCH1, RB1, RECQL, RECQL4, RET, SDHA, SDHAF2, SDHB, SDHC, SDHD, SLX4, SMAD4, SMARCA4, SMARCB1, SUFU, TSC1, TSC2, VHL, EXO1, TMEM127, CDKN1B, CYLD, GRB7, MRE11A, RECQL5, CDKN2B, HOXB12, PIK3CA, PRSS1, SPINK1* |

## 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.

| | |
|---|---|
| aCGH | Array Comparative Genome Hybridization |
| AS PCR | Allele-Specific Polymerase Chain Reaction |
| CGG | Repetitions of nucleotides cytosine (C) and guanine (G) |
| FISH | Fluorescent In Situ Hybridization |

# List of activities within the flexible scope of accreditation

| | |
|---|---|
| KIR | Killer-cell Immunoglobulin-like Receptors |
| MLPA | Multiplex Ligation-dependent Probe Amplification |
| NGS | New Generation Sequencing |
| PCR | Polymerase Chain Reaction |
| PGT-A | Preimplantation Genetic Testing for Aneuploidies |
| PGT-SR | Preimplantation Genetic Testing for familial Structural chromosomal Rearrangements |
| QF PCR | Quantitative- Fluorescent Polymerase Chain Reaction |
| STR | Short Tandem Repeat |