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: 18. 11. 2025

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; SOPV.GP 303, version 005; SOPV.GP 304, version 003; ELISA Reader Opsys MR	Serum	A, B, C
2.	Antisperm antibodies	Agglutination	SOPV.GP 305, version 003; PP.GP 301, version 002	Ejaculate, serum	A, B
3.	Sperm acrosomes	Indirect immunofluorescence	SOPV.GP 306, version 001; PP.GP 301, version 002	Ejaculate	A, B
4.	Anti-ovarian, anti-zonal and anti-spermatozoa antibodies	Indirect immunofluorescence	SOPV.GP 308, version 004; PP.GP 302, version 001	Serum	A, B, C
816 – Medical Genetics Laboratory					
1.	Examination of unbalanced chromosomal aberrations	aCGH	SOPV.GP 101, version 006; PP.GP 101, version 002; PP.GP 102, version 002; PP.GP 103, version 001; PP.GP 702, version 001; PP.GP 705, version 003; SurePrint G3 Unrestricted CGH ISCA v2, 8x60K;	Peripheral and fetal blood, buccal smear, amniotic fluid, chorionic villi and aborted tissue	A, B

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			SurePrint G3 CGH+SNP, 4x180K; SurePrint G3 Unrestricted CGH ISCA v2, 4x180K		
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 002; 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; PP.GP 507, version 003; PP.GP 902, version 001; Miseq platforma Illumina	Trophectoderm	A, B, D
5.	Examination of germline genome variants	AS PCR	SOPV.GP 701, version 002; SOPV.GP 704, version 002; PP.GP 702, version 001; PP.GP 705, version 003; PP.GP 707, version 001; PP.GP 708, version 002; PP.GP 714, version 001; PP.GP 715, version 002; PP.GP 716, version 002; PP.GP 717, version 002; PP.GP 719, version 001; 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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6.	Examination of germline genome variants	Multiplex PCR	SOPV.GP 702, version 002; SOPV.GP 708, version 003; PP.GP 702, version 001; PP.GP 705, version 003; PP.GP 707, version 001; PP.GP 712, version 001; PP.GP 714, version 001; PP.GP 719, version 001; PP.GP 722, version 002; 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; PP.GP 702, version 001; PP.GP 703, version 001; PP.GP 704, version 002; PP.GP 705, version 003; PP.GP 707, version 001; PP.GP 712, version 001; PP.GP 720, version 001; 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; PP.GP 702, version 001; PP.GP 705, version 003; PP.GP 707, version 001; Rotor-Gene RG6000	Peripheral blood, buccal swab	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]
9.	Examination of germline genome variants	PCR with fragment analysis	SOPV.GP 706, version 002; PP.GP 702, version 001; PP.GP 705, version 003; PP.GP 707, version 001; PP.GP 712, version 001; ABI Prism 3500 Genetic Analyzer	Peripheral blood, buccal swab, amniotic fluid (native and cultured), chorionic villi (native and cultured), aborted tissue	A, B
10.	Examination of germline genome variants	Sanger sequencing	SOPV.GP 707, version 002; PP.GP 702, version 001; PP.GP 705, version 003; PP.GP 707, version 001; PP.GP 711, version 001; PP.GP 712, version 001; 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; PP.GP 702, version 001; PP.GP 705, version 003; PP.GP 706, version 001; PP.GP 707, version 001; PP.GP 711, version 001; PP.GP 712, version 001; PP.GP 713, version 002; PP.GP 719, version 001; ABI Prism 3500 Genetic Analyzer	Peripheral blood, buccal swab, amniotic fluid (native and cultured), chorionic villi (native and cultured), aborted tissue	A, B, C

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Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of method procedure/ equipment	Examined material	Degrees of freedom[1]
12.	Examination of germline genome variants	NGS	SOPV.GP 901, version 004; PP.GP 504, version 004; PP.GP 505, version 003; PP.GP 705, version 003; PP.GP 711, version 001; PP.GP 720, version 001; PP.GP 724, version 002; PP.GP 726, version 002; PP.GP 902, version 001; Miseq platform Illumina	Peripheral blood	A, B, C, D
Laboratory examinations for IVF					
1.	Examination of spermiogram	Microscopy; Macroscopy	SOPV.GP 301, version 004	Ejaculate	A, B

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;* HLA typization - alleles and allelic groups: DQ2, DQ8, HLA-B27
816/6	Microdeletion on the Y chromosome; 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,

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	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 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* 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* 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"). Oncopanel – genes: *ATM, APC, BARD1, BRCA1, BRCA2, BRIP1, CDH1, CHEK2, EPCAM, MLH1, MSH2, MSH6, MUTYH, NBN, PALB2, PMS2, PTEN, RAD50, RAD51C, RAD51D, STK11, TP53* *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,*

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	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
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