



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.: 134/2023
Field of Accreditation: Medical laboratory - ČSN EN ISO 15189:2013
Updated: 23/05/2024

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.	Autoantibodies against phospholipids	Immunoassay with photometric detection	SOPV.GP 302, version 002; SOPV.GP 303, version 004; SOPV.GP 304, version 003; ELISA Reader Opsys MR	Serum	A, B, C
2.	Antisperm antibodies	Agglutination	SOPV.GP 305, version 002	Ejaculate, serum, ovulatory secretion	A, B
3.	Sperm acrosomes	Indirect immunofluorescence	SOPV.GP 306, version 001; PP.GP 301, version 001	Ejaculate	A, B
4.	Anti-spermatozoa antibodies	Agglutination	SOPV.GP 307, version 002; PP.GP 302, version 001	Serum	A, B
5.	Anti-ovarian and anti-zonal, anti-sperm antibodies	Indirect immunofluorescence	SOPV.GP 308, version 003; PP.GP 302, version 001	Serum	A, B, C
816 - Medical Genetics Laboratory					



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Ordinal number	Analyte/parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
1.	Examination of germline genome variants	aCGH	SOPV.GP 101, version 003; PP.GP 101, version 001; PP.GP 702, version 001; PP.GP 705, version 002; SurePrint G3 Unrestricted CGH ISCA v2, 8x60K	Peripheral and fetal blood, buccal smear, amniotic fluid, chorionic villi and aborted tissue	A, B
2.	Examination of constitutional karyotype	Cytogenetic analysis	SOPV.GP 102, version 002	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 001; 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 002; PP.GP 507, version 002; 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 002; 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 and fetal blood, buccal smear, amniotic fluid (native and cultivated), chorionic villi (native and cultivated), aborted 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
6.	Examination of germline genome variants	Multiplex PCR	SOPV.GP 702, version 002; SOPV.GP 708, version 002; PP.GP 702, version 001; PP.GP 705, version 002; PP.GP 707, version 001; PP.GP 714, version 001; PP.GP 712, version 001; PP.GP 719, version 001; PP.GP 722, version 002; PP.GP 723, version 002	Peripheral and fetal blood, buccal smear, amniotic fluid (native and cultivated), chorionic villi (native and cultivated), 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 002; PP.GP 707, version 001; PP.GP 712, version 001; PP.GP 720, version 001; ABI Prism 3500 Genetic Analyzer	Peripheral and fetal 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 002; PP.GP 707, version 001; Rotor-Gene RG6000	Peripheral blood, buccal smear	A, B

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9.	Examination of germline genome variants	PCR with fragment analysis	SOPV.GP 706, version 002; PP.GP 702, version 001; PP.GP 705, version 002; PP.GP 707, version 001; PP.GP 712, version 001; ABI Prism 3500 Genetic Analyzer	Peripheral and fetal 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 002; 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 001; 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 procedure/equipment	Examined material	Degrees of freedom ¹
12.	Examination of germline genome variants	NGS	SOPV.GP 901, version 003; PP.GP 504, version 003 PP.GP 505, version 002 PP.GP 705, version 002; PP.GP 711, version 001; PP.GP 720, version 001; PP.GP 724, version 002; PP.GP 726, version 001; Miseq platform Illumina	Peripheral blood	A, B, C, D
Laboratory examination for IVF					
1.	Evaluation of ejaculate	Microscopy; Macroscopy	SOPV.GP 301, version 002	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 (classes IgG and IgM), Annexin V (classes IgG and IgM), Beta2-glycoprotein I (classes IgA and IgG), phosphatidic acid (classes IgG and IgM), phosphatidylethanolamine (classes IgG and IgM), phosphatidylinositol (classes IgG and IgM), phosphatidylserine (classes IgG and IgM)
813/2	antibodies against sperms - MarTest in IgA and IgG classes
813/3	intra acrosomal enzymes
813/4	antibodies against sperms – TAT test
813/5	antibodies against ovaries, against zona pellucida and against spermatozoa (human)
816/4	PGT-A, PGT-SR (24 chromosomes)
816/5	genes: <i>GJB2-35delG</i> , <i>W24X816/2</i> ; HLA typization - alleles and allelic groups: DQ2, DQ8, HLA-B27
816/6	Microdeletion on the Y chromosome; Mutation of CFTR gene: F508del, G542X, N1303K, W1282X, G551D, 1717-1G>A, R553X, CFTRdele2,3(21kb), I507del, 711+1G>T, R560T, 1898+G>A, 3120+1G>A, R347H, R347P, 621+1G>T, 3849+10kbC>T, 2789+5G>A, R1162X, 3659delC, R117H, R117C, R334W, G85E,

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	1078delT, 2183_AA>G, 2184insA, 1677delTA, 2143delT, 3272-26A>G, R1066C, Y1092X(C>A), L1077P, L1065P, T338I, I336K, Intron 8 - 5T(TG9-13)/7T/9T:
816/7	Chromosomes 13, 15, 16, 18, 21, 22, X, Y STR markery: 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: <i>F2</i> (rs1799963), <i>F5</i> (rs6025), <i>MTHFR</i> (rs1801133, rs1801131), <i>PAII</i> (4G/5G)
816/9	Expansion CGG repetition in <i>FMRI</i> gene
816/10	Genes: <i>ATM</i> , <i>APC</i> , <i>BARD1</i> , <i>BRCA1</i> , <i>BRCA2</i> , <i>BRIP1</i> , <i>CDH1</i> , <i>CHEK2</i> , <i>EPCAM</i> , <i>MLH1</i> , <i>MSH2</i> , <i>MSH6</i> , <i>MUTYH</i> , <i>NBN</i> , <i>PALB2</i> , <i>PMS2</i> , <i>PTEN</i> , <i>RAD51C</i> , <i>RAD51D</i> , <i>STK11</i> , <i>TP53</i>
816/11	Genes: <i>ATM</i> , <i>APC</i> , <i>BARD1</i> , <i>BRCA1</i> , <i>BRCA2</i> , <i>BRIP1</i> , <i>CDH1</i> , <i>CHEK2</i> , <i>EPCAM</i> , <i>MLH1</i> , <i>MSH2</i> , <i>MSH6</i> , <i>MUTYH</i> , <i>NBN</i> , <i>PALB2</i> , <i>PMS2</i> , <i>PTEN</i> , <i>RAD51C</i> , <i>RAD51D</i> , <i>STK11</i> , <i>TP53</i> Genes: <i>SMN1</i> , <i>SMN2</i>
816/12	Carrier screening - genes: <i>AR genes</i> (88 genes): <i>ABCA4</i> , <i>ABCC8</i> , <i>ACADM</i> , <i>ACADVL</i> , <i>AGA</i> , <i>AGL</i> , <i>AH11</i> , <i>AIRE</i> , <i>ALDOB</i> , <i>ANO10</i> , <i>ARSA</i> , <i>ASPA</i> , <i>ASS1</i> , <i>ATP7B</i> , <i>BCKDHA</i> , <i>BCKDHB</i> , <i>CAPN3</i> , <i>CATSPER2</i> , <i>CEP290</i> , <i>CFTR</i> , <i>CLN5</i> , <i>CLRN1</i> , <i>CNGA3</i> , <i>CNGB3</i> , <i>COL7A1</i> , <i>CPT1A</i> , <i>CPT2</i> , <i>CYP1B1</i> , <i>CYP21A2</i> , <i>DBT</i> , <i>DHCR7</i> , <i>DLD</i> , <i>DYNC2H1</i> , <i>FAH</i> , <i>FKTN</i> , <i>G6PC</i> , <i>GAA</i> , <i>GALT</i> , <i>GBA</i> , <i>GBE1</i> , <i>GCDH</i> , <i>GJB2</i> , <i>GJB3</i> , <i>GJB6</i> , <i>GLB1</i> , <i>GLE1</i> , <i>GNPTAB</i> , <i>GRIP1</i> , <i>HADHA</i> , <i>HBA1</i> , <i>HBA2</i> , <i>HBB</i> , <i>HEXA</i> , <i>HEXB</i> , <i>HPS1</i> , <i>HPS3</i> , <i>CHRNE</i> , <i>ELP1</i> , <i>KCNJ11</i> , <i>MCOLN1</i> , <i>MEFV</i> , <i>MMUT</i> , <i>MTHFR</i> , <i>MYO7A</i> , <i>NAGA</i> , <i>NEB</i> , <i>NPHS1</i> , <i>OCA2</i> , <i>PAH</i> , <i>PCCA</i> , <i>PCCB</i> , <i>PKHD1</i> , <i>PMM2</i> , <i>POLG</i> , <i>PROPI</i> , <i>RMRP</i> , <i>SERPINA1</i> , <i>SGSH</i> , <i>SLC17A5</i> , <i>SLC26A4</i> , <i>SMN1</i> , <i>SMPD1</i> , <i>STRC</i> , <i>TMEM216</i> , <i>TNXB</i> , <i>TPP1</i> , <i>TYR</i> , <i>USH2A</i> ; <i>X-linked</i> (15 genes): <i>ABCD1</i> , <i>AR</i> , <i>DMD</i> , <i>F8</i> , <i>F9</i> , <i>G6PD</i> , <i>GLA</i> , <i>LICAM</i> , <i>MID1</i> , <i>NR0B1</i> , <i>OTC</i> , <i>PLP1</i> , <i>RPGR</i> , <i>RS1</i> , <i>SLC6A8</i> Reproductive disorders - genes: <i>ANXA5</i> , <i>F2</i> , <i>F5</i> , <i>FSHR</i> , <i>MTHFR</i> (only targeted variants: rs112782763, rs28717001, rs28651243, rs113588187, rs1799963, rs6025, rs6166, rs1801133, rs1801131), <i>AZF_a</i> (regions of STS markers sY83, sY1064, sY86, sY84, genes <i>DDX3</i> and <i>USP9Y</i> and STS marker sY1065), control regions of STS markers sY82, sY88, sY105, <i>AZF_b</i> (region with genomic coordinates: „chrY:18642658-18645962“ and regions of STS markers sY121, sY127, sY134, sY143, sY1192/1191), <i>AZF_c</i> (regions of STS markers sY1192/1191, regions with 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 of STS markers sY14 and region „chrY:56855363-56857442“). Oncopanel - genes: <i>ATM</i>, <i>APC</i>, <i>BARD1</i>, <i>BRCA1</i>, <i>BRCA2</i>, <i>BRIP1</i>, <i>CDH1</i>, <i>CHEK2</i>, <i>EPCAM</i>, <i>MLH1</i>, <i>MSH2</i>, <i>MSH6</i>, <i>MUTYH</i>, <i>NBN</i>, <i>PALB2</i>, <i>PMS2</i>, <i>PTEN</i>, <i>RAD50</i>, <i>RAD51C</i>, <i>RAD51D</i>, <i>STK11</i>, <i>TP53</i>, <i>BAP1</i>, <i>BLM</i>, <i>BMPRIA</i>, <i>CDC73</i>, <i>CDK4</i>, <i>CDKN1C</i>, <i>CDKN2A</i>, <i>DICER</i>, <i>DIS3L2</i>, <i>DPYD</i>, <i>ERCC2</i>, <i>ERCC3</i>, <i>FANCC</i>, <i>FANCM</i>, <i>FH</i>, <i>FLCN</i>, <i>GPC3</i>, <i>KIT</i>, <i>MEN1</i>, <i>MET</i>, <i>MLH3</i>, <i>NF1</i>, <i>NF2</i>, <i>POLD1</i>, <i>POLE</i>, <i>PRKARIA</i>, <i>PTCH1</i>, <i>RBI</i>, <i>RECQL</i>, <i>RECQL4</i>, <i>RET</i>, <i>SDHA</i>, <i>SDHAF2</i>, <i>SDHB</i>, <i>SDHC</i>, <i>SDHD</i>, <i>SLX4</i>, <i>SMAD4</i>, <i>SMARCA4</i>, <i>SMARCB1</i>, <i>SUFU</i>, <i>TSC1</i>, <i>TSC2</i>, <i>VHL</i>, <i>EXO1</i>, <i>TMEM127</i>, <i>CDKN1B</i>, <i>CYLD</i>, <i>GRB7</i>, <i>MRE11A</i>, <i>RECQL5</i>, <i>CDKN2B</i>, <i>HOXB12</i>, <i>PIK3CA</i>, <i>PRSS1</i>, <i>SPINK1</i>



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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.

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	Next-Generation Sequencing / Massive Parallel 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