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: 13/10/2023

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					
1.	Examination of germline genome variants	aCGH	SOPV.GP 101, version 002; 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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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 001; SOPV.GP 704, version 001; PP.GP 702, version 001; PP.GP 705, version 001; PP.GP 707, version 001; PP.GP 708, version 001 PP.GP 714, version 001; PP.GP 715, version 001; PP.GP 716, version 001; PP.GP 717, 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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6.	Examination of germline genome variants	Multiplex PCR	SOPV.GP 702, version 001; SOPV.GP 708, version 001; PP.GP 702, version 001; PP.GP 705, version 001; PP.GP 707, version 001; PP.GP 714, version 001; PP.GP 712, version 001; PP.GP 719, version 001; PP.GP 722, version 001; PP.GP 723, version 001;	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 001; PP.GP 702, version 001; PP.GP 703, version 001; PP.GP 704, version 001; PP.GP 705, version 001; PP.GP 707, version 001; PP.GP 712, version 001;	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 001; PP.GP 702, version 001; PP.GP 705, version 001; PP.GP 707, version 001;	Peripheral blood, buccal smear	A, B
9.	Examination of germline genome variants	PCR with fragment analysis	SOPV.GP 706, version 001; PP.GP 702, version 001; PP.GP 705, version 001; PP.GP 707, version 001; PP.GP 712, version 001;	Peripheral and fetal blood, buccal swab, amniotic fluid (native and cultured), chorionic villi (native and cultured), aborted tissue	A, B

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10.	Examination of germline genome variants	Sanger sequencing	SOPV.GP 707, version 001; PP.GP 702, version 001; PP.GP 705, version 001; PP.GP 707, version 001; PP.GP 711, version 001; PP.GP 712, version 001;	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 001; 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 001; PP.GP 719, version 001;	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 002 PP.GP 504, version 002 PP.GP 505, version 002 PP.GP 724, 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),

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	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: *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: 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, 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	Thrombophilic mutation - genes: *F2, F5, MTHFR, PAI1*
816/9	Expansion CGG repetition in *FMR1* gene
816/10	Oncopanel - genes: *ATM, APC, BARD1, BRCA1, BRCA2, BRIP1, CDH1, CHEK2, EPCAM, MLH1, MSH2, MSH6, MUTYH, NBN, PALB2, PMS2, PTEN, RAD50, RAD51C, RAD51D, STK11, TP53*
816/11	Oncopanel - genes: *ATM, APC, BARD1, BRCA1, BRCA2, BRIP1, CDH1, CHEK2, EPCAM, MLH1, MSH2, MSH6, MUTYH, NBN, PALB2, PMS2, PTEN, RAD50, RAD51C, RAD51D, STK11, TP53* Geny: *SMN1, SMN2*
816/12	Carrier screening - genes: *AR genes (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-linked (15 genes): ABCD1, AR, DMD, F8, F9, G6PD, GLA, L1CAM, MID1, NR0B1, OTC, PLP1, RPGR, RS1, SLC6A8*

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	Reproductive disorders - genes: *ANXA5, F2, F5, FSHR, MTHFR (only targeted variants: rs112782763, rs28717001, rs28651243, rs113588187, rs1799963, rs6025, rs6166, rs1801133, rs1801131), AZFa (regions of STS markers sY83, sY1064, sY86, sY84, genes DDX3 and USP9Y and STS marker sY1065), control regions of STS markers sY82, sY88, sY105, AZFb (region with genomic coordinates: „chrY:18642658-18645962“ and regions of STS markers sY121, sY127, sY134, sY143, sY1192/1191), AZFc (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“).*

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