List of activities within the flexible scope of accreditation

Accredited Body: REPROMEDA s.r.o.

CAB Name: Laboratory of Medical and Reproductive Genetics

CAB Number: 8153

Certificate of Accreditation No.: 564/2024

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

Updated: 23.6.2025

Examinations:

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of method procedure/ equipment	Examined material	Degrees of freedom[1]
816 – Medical Genetics Laboratory					
1.	Examination of constitutional karyotype	Conventional cytogenetic analysis	SOP 00452, version 14; SOP 00453, version 6	Peripheral blood	A, B
2.	Examination of unbalanced chromosomal aberrations	NGS-MPS	SOP 00416, version 5; SOP 00401, version 7; SURFSeq 5000Dx, GeneMind platform	Blastomeres, polar bodies, trophoblast cells	A, B, C, D
3.	Preimplantation genetic testing of germline genome variants (PGT)	Karyomapping	SOP 00408, version 3; SOP 00401, version 7; iScan System Illumina	Blastomeres, polar bodies, trophoblast cells, peripheral blood, buccal swab, saliva, isolated DNA	A, B, C, D
4.	SMN1 gene examination	MLPA	SOP 00414, version 2; SOP 00401, version 7	Peripheral blood, isolated DNA, buccal swab, saliva	A, B, D
5.	Examination of germline genome variants	NGS-MPS	SOP 00417, version 6; SOP 00401, version 7; SURFSeq 5000Dx, GeneMind platform	Peripheral blood, isolated DNA, buccal swab, saliva	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	NGS-MPS	SOP 00422, version 4; SOP 00401, version 7; SURFSeq 5000Dx, GeneMind platform	Peripheral blood, isolated DNA, buccal swab, saliva	A, B, C, D

Specification of the scope of accreditation:

Field Nr. / Ordinal Number	Detailed information on activities within the scope of accreditation
816/3	Testing for aneuploidies and structural aberrations, testing for aneuploidies and monogenic diseases
816/4	Copy numbers of exons 7 and 8
816/5	*CFTR*, *GJB2*, *SMN1* (copy numbers of exons 7 a 8), *FV* G1691A (Leiden), *FV* A4070G (H1299R, R2), *Protrombin* G20210A, *MTHFR* C677T, *MTHFR* A1298C, *PAI-1* 4G/5G, *ANXA5* (haplotypes WT, M1 a M2), *FSHR* (c.2039G>A, c.-29G>A), *LHCGR* (insLQp.18, c.872A>G), *LHB* (c.82T>C, c.104T>C), *PLK4* (c.1671+135A>G), Y chromosome microdeletion (*SRY*, *ZFY*, *AZFa*_DYS148, *AZFa*_G65849, *AZFa*_DDX3Y, *AZFb*_DYS218, *AZFb*_DYS222, *AZFb*_DYS224, *AZFc*_sY1035 ~ *BPY2*_ex 6, *AZFc*_SY254 ~ *DAZ* 1-4, *AZFc*_sY1291)
816/6	*NGS panel PANDA® Carrier genes:* *ABCA3, ABCA4, ABCC6, ABCC8, ACADM, ACADS, ACADVL, AGL, AGXT, ALDOB, ALPL, AR, ARSA, ASL, ASPA, ASS1, ATM, ATP7B, BCKDHA, BCKDHB, BCS1L, BLM, BTD, CAPN3, CBS, CFTR, CLN3, CNGB3, COL4A3, COL4A5, COL7A1, CPT2, CTNS, CYP21A2, CYP27A1, DHCR7, DLD, DMD, ELP1, F8, F9, F11, FAH, FANCA, FANCC, FMR1, G6PC, GAA, GALC, GALT, GBA, GCDH, GJB2, GLA, GLB1, GNPTAB, HADHA, HBA1/HBA2, HBB, HEXA, IDUA, IL2RG, LAMB3, MCCC1, MCCC2, MCOLN1, MEFV, MMACHC, MUT, MTM1, MVK, MYO7A, NAGLU, NBN, NPC1, NPHS2, OTC, PAH, PCDH15, PEX1, PEX6, PEX7, PEX12, PKHD1, PMM2, POLG, PPT1, PROP1, RNASEH2B, SBDS, SERPINA1, SGSH, SLC26A2, SLC26A4, SLC37A4, SMN1, SMPD1, TGM1, TMEM216, TPP1, TSHR, TYR, USH2A, USH1C, XPC, FV* G1691A (Leiden), *FV* A4070G (H1299R, R2), *Protrombin* G20210A, *MTHFR* C677T, *MTHFR* A1298C, *PAI-1* 4G/5G, *ANXA5* (haplotypes WT, M1 a M2), *FSHR* (c.2039G>A, c.-29G>A), *LHCGR* (insLQp.18, c.872A>G), *LHB* (c.82T>C, c.104T>C), *PLK4* (c.1671+135A>G), Y chromosome microdeletion (*SRY*, *ZFY*, *AZFa*_DYS148, *AZFa*_G65849, *AZFa*_DDX3Y, *AZFb*_DYS218, *AZFb*_DYS222, *AZFb*_DYS224, *AZFc*_sY1035 ~ *BPY2*_ex 6, *AZFc*_SY254 ~ *DAZ* 1-4, *AZFc*_sY1291) *NGS panel ILGA™ for male (infertility linked genotype analysis) genes:* *ACTL7A, ACTL9, ADGRG2, AMHR2, ANOS1, AR, AURKC, CATSPER1, CATSPER2, CFAP43, CFAP44, CFAP69, CFTR, DNAH1, DPY19L2, FANCM, FEZF1, FGF17, FGF8, FGFR1, FLRT3, FSHB, FSHR, GNRH1, GNRHR, HESX1, HS6ST1, IL17RD, INSL3, IQCN, KISS1R, KLHL10, LHB, LHCGR,*

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	LHX3, LHX4, M1AP, NANOS1, NR0B1, NR5A1, NSMF, PLCZ1, PMFBP1, PROK2, PROKR2, PROP1, SEMA3A, SLC26A8, SOHLH1, SOX3, SPATA16, SRY, STAG3, SUN5, SYCE1, SYCP3, TAC3, TACR3, TAF4B, TEX11, TEX14, TEX15, USP26, USP9Y, WDR11, ZMYND15, chr Y mikrodelece - *AZF a,b,c.* *NGS panel ILGA™ for female (infertility linked genotype analysis) genes:* *AR, BMP15, CDC20, CLPP, CYP11A1, CYP17A1, CYP19A1, EIF2B2, EIF2B4, EIF2B5, ESR1, FANCM, FIGLA, FLCN, FMR1, FOXL2, FSHB, FSHR, GALT, GDF9, GNRH1, GNRHR, HARS2, HFM1, HSD17B4, KISS1, KISS1R, LARS2, LHB, LHCGR, MCM8, MCM9, NLRP5, NOBOX, NR0B1, NR5A1, NUP107, PADI6, PATL2, POF1B, PSMC3IP, REC114, SOHLH1, STAG3, SYCE1, TACR3, TLE6, TUBB8, WEE2, ZP1, ZP2, ZP3.* *NGS panel CZECANCA genes:* *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* *NGS panel EXOM:* *for the analysis of all human genes*

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.

NGS-MPS	Massively parallel sequencing
MLPA	Multiplex Ligation-dependent Probe Amplification

"This document is an appendix to the certificate of accreditation. In case of any discrepancies between the English and Czech versions, the Czech version shall prevail, both for the certificate appendix and the certificate itself. "