The Appendix is an integral part of
Certificate of Accreditation No. 123/2018 of 15/03/2018

Accredited entity according to ČSN EN ISO 15189:2013:

PRONATAL, s.r.o.
PRONATAL Sanatorium Genetics Laboratory
Pekárkova 14, 143 00, Praha 4

The Laboratory has a flexible scope of accreditation permitted as detailed in the Annex. Updated list of activities provided within the flexible scope of accreditation is available at the Laboratory from the Laboratory Manager.

Examinations:

Ordinal number	Examination procedure name	Examination procedure identification	Examined object
816 - Medical Genetics Laboratory			
1.	Examination of chromosomal aberrations by FISH method	3-SOP-SP-14	Peripheral blood, amniotic fluid cells, chorion biopsy, product of conception, abortion tissue, umbilical blood
2.	Preimplantation screening of aneuploidies of 24 chromosomes by array CGH method	3-SOP-SP-19	Blastomeres, trophectoderm cells
3.	Preimplantation diagnostics of structural chromosomal aberations by FISH method (*20)	3-SOP-SP-20	Blastomeres, trophectoderm cells
4.	Karyotyping from peripheral blood, umbilical blood, amniotic fluid cells, chorion biopsy and abortion tissue	3-SOP-SP-24	Peripheral blood, amniotic fluid cells, chorion biopsy, product of conception, abortion tissue, umbilical blood
5.	Examination of thrombophilic mutations by real-time PCR method (*30)	3-SOP-SP-30	Biological material containing human nuclear DNA
6.	Examination of CFTR gene mutations by fluorescent multiplex PCR method (*34)	3-SOP-SP-34	Biological material containing human nuclear DNA
7.	Examination of chromosome Y microdeletions by fluorescent multiplex PCR method (*36)	3-SOP-SP-36	Biological material containing human nuclear DNA
8.	Examination of 13, 18, 21, X and Y chromosome aneuploidies by QF PCR method (*37)	3-SOP-SP-37	Biological material containing human nuclear DNA

The Appendix is an integral part of
Certificate of Accreditation No. 123/2018 of 15/03/2018

Accredited entity according to ČSN EN ISO 15189:2013:

PRONATAL, s.r.o.
PRONATAL Sanatorium Genetics Laboratory
Pekárkova 14, 143 00, Praha 4

Ordinal number	Examination procedure name	Examination procedure identification	Examined object
9.	Direct detection of DNA of bacteria with relation to infertility from cervical and urethral swab and urine by real-time PCR method (*38)	3-SOP-SP-38	Cervical and urethral swab, urine
10.	Direct detection of HCV virus RNA by real-time PCR method	3-SOP-SP-39	Serum, plasma
11.	Direct detection of HBV virus DNA by real-time PCR method	3-SOP-SP-40	Serum, plasma
12.	Examination of exon 7 and 8 deletion in SMN1 gene by MLPA method	3-SOP-SP-41	Biological material containing human nuclear DNA
13.	Preimplantation screening of aneuploidies of 24 chromosomes and preimplantation diagnostics of structural chromosomal aberations by MPS method	3-SOP-SP-42	Blastomeres, trophectoderm cells
14.	Examination of selected genes by MPS method (*43)	3-SOP-SP-43	Peripheral blood, biological material containing human nuclear DNA
15.	Examination of selected genes by MLPA method (*44)	3-SOP-SP-44	Peripheral blood, biological material containing human nuclear DNA
16.	Preimplantation genetic diagnostics of monogenic diseases by PGH method (*46)	3-SOP-SP46	Blastomeres, trophectoderm cells

Annex:
Flexible scope of accreditation

Examination procedure ordinal numbers
(SOP19), 6 (SOP34), 7 (SOP36), 8 (SOP37), 9 (SOP38), 14 (SOP43), 15 (SOP44), 16(SOP46)

The Laboratory is allowed to modify the examination procedures listed in the Annex within the specified scope of accreditation provided the measuring principle is observed.

The flexible approach to the scope of accreditation cannot be applied to the examinations not included in the Annex.

Accredited entity according to ČSN EN ISO 15189:2013:

PRONATAL, s.r.o.
PRONATAL Sanatorium Genetics Laboratory
Pekárkova 14, 143 00, Praha 4

Explanations and abbreviations:

FISH	Fluorescent *In situ* Hybridization
CGH	Comparative Genomic Hybridization
PCR	Polymerase Chain Reaction
QF PCR	Quantitative Fluorescent PCR
AZF	Azoospermic Factor
MPS	Massively Parallel Sequencing
MLPA	Multiplex Ligation-dependent Probe Amplification
PGH	Preimplantation Genetic Haplotyping
SMN	gene for spinal muscular atrophy

*20 Examination of chromosome X, Y, 13, 15, 16, 18, 21, 22 aneuploidies, examination of reciprocal translocations and inversions

*30 Examination of the following mutations: Factor V gene Leiden mutation (G1691A) and factor II gene mutation (G20210A) (prothrombin)

*34 Examination of the following mutations in the gene for for cystic fibrosis (CFTR): CFTRdele2,3; R334W; R553X; Y1092X (C> A); E60X; R347p; R560T; M1101K; P67L;R347H; 1811+1.kbA> G; D1152H; G85E; A455E; 1898+1G> A; R1158X; 394delTT; 1507del; 2143delT; R1162X; 444delA; F508del; 2184delA; 3659delC; R117C; 1677delTA; 2347delG; 3849+10kb C> T; R117H; V520F; W846X; S1251N; Y122X; 1717-1G> A; 3905insT; 621+1G> T; G542X; Q890X; W1282X; 711+1G> T; S549R(T> G); 3120+1G> A; N1303K; L206W; S549N; 3272-26A> G; Intron 8 – 5T/7T/9T; 1078delT; G551D; R1066C.

*36 Examined loci: Yp11.3(SRY,ZFY); AZFa(sY84,sY86); AZFb(sY127,sY134); AZFc(sY254,sY255)

*37 Examined loci: D13S742, D13S634, D13S634, D13S628, D13S1492, D18S978, D18S535, D18S386, GATA178F11, D18S1364, D21S1435, D21S11, D21S1411, D21S1444, D13S800, D13S252, D18S386, D18S1002, D18S976, D21S1446, D21S2055, DXS1187, DXS1187, DXS981, XHPRT, DXS2390, DXYS267, DXYS218, AMELX, AMELY, ZFY, ZFX, SRY, T1(7q34,Xq13), T3(3p24.2,Xq21.1)

*38 *Chlamydia trachomatis, Mycoplasma hominis, Ureaplasma species*

*43 Examined genes: AIP, ALK, APC, APEX1, ATM, ATMIN, ATR, ATRIP, AURKA, AXIN1, BABAM1, BAP1, BARD1, BLM, BMPR1A, BRAP, BRCA1, BRCA2, BRCC3, BRE, BRIP1, BUB1B, C11ORF30, C19ORF40, CASP8, CCND1, CDC73, CDH1, CDK4, CDKN1B, CDKN1C, CDKN2A, CEBPA, CEP57, CLSPN, CSNK1D, CSNK1E, CWF19L2, CYLD, DCLRE1C, DDB2, DHFR, DICER1, DMC1, DNAJC21, DPYD,

Accredited entity according to ČSN EN ISO 15189:2013:

PRONATAL, s.r.o.
PRONATAL Sanatorium Genetics Laboratory
Pekárkova 14, 143 00, Praha 4

EGFR, EPCAM, EPHX1, ERCC1, ERCC2, ERCC3, ERCC4, ERCC5, ERCC6, ESR1, ESR2, EXO1, EXT1, EXT2, EYA2, EZH2, FAM175A, FAM175B, FAN1, FANCA, FANCB, FANCC, FANCD2, FANCE, FANCF, FANCG, FANCI, FANCL, FANCM, FBXW7, FH, FLCN, GADD45A, GATA2, GPC3, GRB7, HELQ, HNF1A, HOXB13, HRAS, HUS1, CHEK1, CHEK2, KAT5, KCNJ5, KIT, LIG1, LIG3, LIG4, LMO1, LRIG1, MAX, MCPH1, MDC1, MDM2, MDM4, MEN1, MET, MGMT, MLH1, MLH3, MMP8, MPL, MRE11A, MSH2, MSH3, MSH5, MSH6, MSR1, MUS81, MUTYH, NAT1, NBN, NCAM1, NELFB, NF1, NF2, NFKBIZ, NHEJ1, NSD1, OGG1, PALB2, PARP1, PCNA, PHB, PHOX2B, PIK3CG, PLA2G2A, PMS1, PMS2, POLB, POLD1, POLE, PPM1D, PREX2, PRF1, PRKAR1A, PRKDC, PTCH1, PTEN, PTTG2, RAD1, RAD17, RAD18, RAD23B, RAD50, RAD51, RAD51B, RAD51C, RAD51D, RAD51AP1, RAD52, RAD54B, RAD54L, RAD9A, RB1, RBBP8, RECQL, RECQL4, RECQL5, RET, RFC1, RFC2, RFC4, RHBDF2, RNF146, RNF168, RNF8, RPA1, RUNX1, SDHAF2, SDHB, SETBP1, SETX, SHPRH, SLX4, SMAD4, SMARCA4, SMARCB1, SMARCE1, STK11, SUFU, TCL1A, TELO2, TERF2, TERT, TLR2, TLR4, TMEM127, TOPBP1, TP53, TP53BP1, TSC1, TSC2, TSHR, UBE2A, UBE2B, UBE2I, UBE2V2, UBE4B, UIMC1, VHL, WRN, WT1, XPA, XPC, XRCC1, XRCC2, XRCC3, XRCC4, XRCC5, XRCC6, ZNF350, ZNF365

*44 Examined genes: BRCA 1

*46 Implemented procedures for PGD of monogenic diseases: Adrenogenital syndrome, Aicardi-Goutiere, Achondroplasia, APKD-polycystic kidney disease, BRCA1, CFTR, CMT, CMTX1,Connexin 26, DMD, Ehlers–Danlos syndrome, Ectrodactylia, FRA11B, FRAXA, FSHD, Haemophilia, Incontinentia pigmenti, Adrenoleukodystrophy, Huntington, Hyperekplexia, Hypokalemic paralysis, Ichtyosis, Jeune syndrome, Krabbe disease, Lynch syndrome, Marfan, Muscle-eye-brain sy., DMPK1-myotonic dystrophy, NF1,2, Prader-Willi, Sandhoff dis., SLOS, SMA, Spinocerebellar ataxia, Testicular feminization syndrome-Argen, Treacher Collins Syndrome, Tuberous sclerosis, Von Hippel Lindau