The Appendix is an integral part of
Certificate of Acreditation No. 303/2020 of 12/05/2020

Acredited entity according to ČSN EN ISO 15189:2013:

PRONATAL, s.r.o.
PRONATAL Sanatorium Genetics Laboratory
Pekárkova 261/14, 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.

Examination:

Ordinal number	Examination procedure name	Examination procedure identification	Examined object
802 - Clinical microbiology			
1.	Direct detection of DNA of bacteria with relation to infertility from cervical and urethral swab and urine by real-time PCR method [1)]	3-SOP-SP-38	Cervical and urethral swab, urine
2.	Direct detection of HCV virus RNA by real-time PCR method	3-SOP-SP-39	Serum, plasma
3.	Direct detection of HBV virus DNA by real-time PCR method	3-SOP-SP-40	Serum, plasma
816 - Laboratory of clinical genetics			
1.	Examination of chromosomal aberrations by FISH method	3-SOP-SP-14	Peripheral blood, amniotic fluid cells, chorion biopsy, abortion tissue, umbilical blood
2.	Preimplantation diagnostics of structural chromosomal aberrations (PGT-SR) by FISH method [2)]	3-SOP-SP-20	Blastomeres, trophectoderm cells
3.	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
4.	Examination of trombophilic mutations by real-time PCR method [3)]	3-SOP-SP-30	Biological material containing human nuclear DNA

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Ordinal number	Examination procedure name	Examination procedure identification	Examined object
5.	Examination of selected gene mutations by fluorescent multiplex PCR method and follow-up DNA fragment analysis [4)]	3-SOP-SP-34	Biological material containing human nuclear DNA
6.	Examination of chromosome Y microdeletions by fluorescent multiplex PCR method [5)]	3-SOP-SP-36	Biological material containing human nuclear DNA
7.	Examination of 13, 18, 21, X and Y chromosome aneuploidies by QF PCR method [6)]	3-SOP-SP-37	Biological material containing human nuclear DNA
8.	Examination of exon 7 and 8 deletion in *SMN1* gene by MLPA method	3-SOP-SP-41	Biological material containing human nuclear DNA
9.	Preimplantation screening of aneuploidies of 24 chromosomes (PGT-A) and preimplantation diagnostics of structural chromosomal aberrations (PGT-SR) by NGS method	3-SOP-SP-42	Blastomeres, trophectoderm cells
10.	Examination of selected genes by MPS method [7)]	3-SOP-SP-43	Peripheral blood, biological material containing human nuclear DNA
11.	Examination of selected genes by MLPA method [8)]	3-SOP-SP-44	Peripheral blood, biological material containing human nuclear DNA
12.	Preimplantation genetic diagnostics of monogenic diseases (PGT-M) by PGH method and follow-up DNA fragment analysis [9)]	3-SOP-SP46	Blastomeres, trophectoderm cells

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Annex:
Flexible scope of accreditation

Examination procedure ordinal numbers
In the field 802 : 1
In the field 816: 5, 6, 7, 10, 11, 12

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.

Explanations and abbreviations:

FISH	Fluorescent *In situ* Hybridization
CGH	Comparative Genomic Hybridization
PCR	Polymerase Chain Reaction
QF PCR	Quantitative Fluorescent PCR
AZF	Azoospermic Factor
MLPA	Multiplex Ligation-dependent Probe Amplification
NGS	Next Generation Sequencing
PGH	Preimplantation Genetic Haplotyping
PGT-A	Preimplantation Genetic Testing of aneuploidies
PGT-SR	Preimplantation Genetic Testing of Structural Rearrangements
PGT-M	Preimplantation Genetic Testing of Monogenic Diseases
SMN	Gene for spinal muscular atrophy

1) *Chlamydia trachomatis, Mycoplasma hominis, Ureaplasma species*

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

3) Examination of the following mutations: Factor V gene (*F5*) Leiden mutation (G1691A) and factor II gene mutation (G20210A) (prothrombin) (*F2*)

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4) Examination of the following mutations in the gene for cystic fibrosis (CFTR): c.54-5940_273+10250del21080 (CFTRdele2,3); c.178G>T (E60X); c.200C>T (P67L); c.254G>A (G85E); c.262_263delTT (394delTT); c.313delA (444delA); c.349C>T (R117C); c.350G>A (R117H); c.366T>A (Y122X);c.489+1G>T(621+1G>T); c.579+1G>T (711+1G>T); c.617T>G (L206W); c.948delT (1078delT); c.1000C>T (R334W); c.1040G>C (R347P); c.1040G>A (R347H); c.1364C>A (A455E); c.1519_1521delATC (I507del); c.1521_1523delCTT (F508del); c.1545_1546delTA (1677delTA); c.1558G>T (V520F); c.1585-1G>A (1717-1G>A); c.1624G>T (G542X); c.1647T>G (S549R(T>G)); c.1646G>A (S549N); c.1652G>A (G551D); c.1657C>T (R553X); c.1679G>C (R560T); c.1680-886A>G (1811+1.6kbA>G); c.1766+1G>A (1898+1G>A); c.2012delT (2143delT); c.2052delA (2184delA); c.2215delG (2347delG); c.2538G>A (W846X); c.2657+5G>A (2789+5G>A); c.2668C>T (Q890X); c.2988+1G>A (3120+1G>A); c.3140-26A>G (3272-26A>G); c.3196C>T (R1066C); c.3276C>A (Y1092X(C>A)); c.3302T>A (M1101K); c.3454G>C (D1152H); c.3472C>T (R1158X); c.3484C>T (R1162X); c.3528delC (3659delC); c.3718-2477C>T (3849+10kbC>T); c.3752G>A (S1251N); c.3773dupT (3905insT); c.3846G>A (W1282X); c.3909C>G (N1303K); c.1210-12T(5)/(7)/(9) (IVS9-5T; IVS9-7T a IVS9-9T). Reference sequence: NM_000492.3

Examination of mutation 35delG in gene G*JB2* for connexin 26

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

6) 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)

7) Examined genes of the **CZECANCA panel**: *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, 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,*

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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

Examined diseases and genes of the **Compa-test panel**: short-chain, middle-chain and very-long chain acyl-CoA dehydrogenase deficiency (*ACADM, ACADS, ACADVL*), Usher syndrome (*HADHA, ADGRV1, MYO7A, PCDH15, USH1C, USH2A, CDH23, CLRN1*), Cori disease (*AGL*), Hypophosphatase (*ALPL*), ANXA5 M2 haplotype, Androgene insensitivity syndrome (*AR*), Metachromatic leucodystrophy (*ARSA*), Argininosuccinate-lyase deficiency (*ASL*), Canavan disease (*ASPA*), Citrullinemia type I (*ASS1*), Ataxia-Telangiectasia (*ATM*), Wilson disease (*ATP7B*), Microdeletion in AZF regions on chromosome Y (*AZFdel*), Bloom syndrome (*BLM*), Biotinidase deficiency (*BTD*), Homocystinuria classical (*CBS*), Cystic fibrosis (*CFTR*), Myasthenic syndrome congenital (*CHRNE*), Alport syndrome (*COL4A5*), Cystinosis (*CTNS*), 21-hydroxylase deficiency (*CYP21A2*), Cerebrotendinous xanthomatosis (*CYP27A1*), Smith-Lemli-Opitz syndrome (*DHCR7*), Trombophilic mutation c.20210G>A in the gene for prothrombin (*F2*), Trombophilic mutation c.1691G>A (Leiden) in the gene for FV (*F5*), Tyrosinemia (*FAH*), Polymorphisms p.Ser680Asn in the gene for receptor FSH (*FSHR*), Hepatorenal glykonenosis type 1A von Gierke (*G6PC*), Galactosemia (*GALT*), Gaucher disease (*GBA*), Glutaric acidemia, type 1 (*GCDH*), Non-syndromic hearing loss (*GJB2*), Fabry disease (*GLA*), GM1-gangliosidosis (*GLB1*), Mucolipidosis II-III (*GNPTAB*), Beta-thalasemia (*HBB*), Hemoglobinopathy E (*HBB*), Sickle-Cell Anemia (*HBB*), Tay-Sachs disease (*HEXA*), Hemochromatosis (*HFE*), Mucopolysacharidosis type I (*IDUA*), X-linked Severe Combined Immunodeficiency Disease) (*IL2RG*), 3-Methylcrotonyl-CoA carboxylases deficiency (*MCCC1, MCCC2*), Mediterranean fever (*MEFV*), MTHFR Deficiency (*MTHFR*), Myotubular myopathy, X-linked (*MTM1*), Nijmegen Breakage Syndrome (*NBN*), Niemann-Pick disease (*NPC1, NPC2, SMPD1*), X-linked Deficiency of Ornithin transcarbamylase (*OTC*), Phenylketonuria (*PAH*), Zellweger Syndrome Spectrum (*PEX1, PEX2, PEX6, PEX10, PEX12, PEX13, PEX14, PEX16*), Chondrodysplasia punctata (*PEX7*), Congenital glycosylation disorder (*PMM2-CDG*), Alpha-1 antitrypsine deficiency (*SERPINA1*), Mucopolysacharidosis type IIIA (*SGSH*), Pendred syndrome (*SLC26A4*), Spinal muscular atrophy (*SMN1*), Lamellar ichtyosis (*TGM1*), Neuronal ceroid lipofuscinosis (*TPP1*)

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8) Examined genes: *BRCA 1, BRCA2, CHEK2, NF1*

9) Implemented procedures for PGT-M of monogenic diseases:
21-hydroxylase deficiency (Adrenogenital syndrome, *CYP21A2)*, Aicardi-Goutiere syndrome, Achondroplasia, Polycystic kidney disease, Hereditary breast and ovarian cancer, Cystic fibrosis (*CFTR*), Charcot-Marie-Tooth (*PMP22, CMTX1*), Non-syndromic deafness (gene *GJB2* for connexin 26), Duchenne muscular dystrophy (*DMD*), Ehlers-Danlos syndrome, Ectrodactylia, FRA11B, FRAXA syndrome, FSHD, Haemophilia, Incontinentia pigmenti, Adrenoleukodystrophy, Huntington disease, Hyperekplexia, Hypokalemic paralysis, Ichtyosis, Jeune syndrome, Krabbe disease, Lynch syndrome, Marfan syndrome, Muscle-eye-brain syndrome, Myotonic dystrophy (*DMPK1*), Neurofibromatosis (*NF1*, *NF2*), Prader-Willi syndrome, Sandhoff disease, Smith-Lemli-Opitz syndrome (SLOS, *DHCR7* gene), Spinal muscular atrophy (*SMN1*), Spinocerebellar ataxia, Testicular feminization syndrome (*AR*), Treacher-Collins Syndrome, Tuberous sclerosis, Von Hippel Lindau syndrome.

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