The Appendix is an integral part of
Certificate of Accreditation No. 508/2021 of 29/09/2021

Accredited 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.

Examinations:

Ordinal number	Examination procedure name	Examination procedure identification	Examined object
	802 - Medical microbiology		
1.	Direct detection of DNA of bacteria with relation to infertility by real-time PCR method [1)]	3-SOP-SP-38	Cervical and urethral swab, urine
2.	Direct detection of viral nucleic acids by real-time PCR method [2)]	3-SOP-SP-39	Serum, plasma, mucosal smears, saliva
	816 - Medical Genetics Laboratory		
1.	Examination of chromosomal aberrations by FISH method	3-SOP-SP-14	Peripheral blood, amniotic fluid cells, chorion biopsy, abortion tissue, umbilical blood
2.	Reserved		
3.	Examination of karyotype	3-SOP-SP-24	Peripheral blood, amniotic fluid cells, chorion biopsy, abortion tissue, umbilical blood
4.	Examination of thrombophilic mutations by real-time PCR method[3)]	3-SOP-SP-30	Biological material containing human nuclear DNA
5.	Examination of mutations of selected genes by fluorescent multiplex PCR method with subsequent 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

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Ordinal number	Examination procedure name	Examination procedure identification	Examined object
8.	Reserved		
9.	Preimplantation genetic testing of aneuploidies of 24 chromosomes (PGT-A) and preimplantation genetic testing of structural chromosomal aberations (PGT-SR) by NGS method	3-SOP-SP-42	Blastomeres, trophectoderm cells
10.	Examination of selected genes by NGS 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 testing of monogenic diseases (PGT-M) by PGH method with subsequent fragment analysis [9)]	3-SOP-SP-46	Blastomeres, trophectoderm cells

Annex:
Flexible scope of accreditation

Examination procedure ordinal numbers:
In the field of expertise 802: 1, 2
In the field of expertise 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

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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 Aberations
PGT-M	Preimplantation Genetic Testing of Monogenic Diseases
SMN	gene for Spinal Muscular Atrophy

Specification of the scope of accreditation

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

2) Hepatitis B virus, Hepatitis C virus, SARS-CoV-2 virus

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

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 sequences: NM_000492.3

   Examination of 35delG mutation in *GJB2* gene 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,

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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 panel **CZECANCA version 1.2**: *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, 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 panel **Compa-test version 3**: Deficiency of Acyl-CoA dehydrogenases of medium, short and very long chain fatty acids (*ACADM, ACADS, ACADVL*), Usher syndrome (*HADHA, ADGRV1, MYO7A, PCDH15, USH1C, USH2A, CDH23, CLRN1*), Cori's disease (*AGL*), Hypophosphatasia (*ALPL*), ANXA5 M2 haplotype, Androgen insensitivity syndrome (*AR*), Metachromatic leukodystrophy (*ARSA*), Argininosuccinate lyase deficiency (*ASL*), Canavan disease (*ASPA*), Citrullinemia type I (*ASS1*), Ataxia-telangiectasia (*ATM*), Wilson's disease (*ATP7B*), Bloom's syndrome (*BLM*), Biotinidase deficiency (*BTD*), Classic homocystinuria (*CBS*), Cystic fibrosis (*CFTR*), Congenital myasthenic syndrome (*CHRNE*), Alport syndrome (*COL4A5*), Cystinosis (*CTNS*), 21-hydroxylase deficiency (*CYP21A2*), Cerebrotendinous xanthomatosis (*CYP27A1*), Smith-Lemli-Opitz syndrome (*DHCR7*), Thrombophilic mutation c. 20210G>A in prothrombin gene (*F2*), Thrombophilic mutation c.1691G>A (Leiden) in the gene for FV (*F5*), Tyrosinemia (*FAH*), Polymorphism p. Ser680Asn in FSH receptor gene (*FSHR*), Hepatorenal glycogenosis type1A von Gierke (*G6PC*), Galactosemia (*GALT*), Gaucher disease (*GBA*), Glutaric acidemia type 1 (*GCDH*), Nonsyndromic hearing loss (*GJB2*), Fabry disease (*GLA*), GM1-gangliosidosis (*GLB1*), Mucolipidosis II-III (*GNPTAB*), Beta thalassemia (*HBB*), Hemoglobinopathy E (*HBB*),

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Sickle cell anemia (*HBB*), Tay-Sachs disease (*HEXA*), Hemochromatosis (*HFE*), Mucopolysaccharidosis type I (*IDUA*), X-linked severe combined immunodeficiency (*IL2RG*), 3-Methylcrotonyl-CoA carboxylase deficiency (*MCCC1, MCCC2*), Mediterranean Fever (*MEFV*), Myotubular Myopathy, X-linked (*MTM1*), Nijmegen Breakage Syndrome (*NBN*), Niemann-Pick Disease (*NPC1, NPC2, SMPD1*), X-linked ornithine transcarbamylase deficiency (*OTC*), Phenylketonuria (*PAH*), Zellweger Syndrome Spectrum (*PEX1, PEX2, PEX6, PEX10, PEX12, PEX13, PEX14, PEX16*), Chondrodysplasia punctata (*PEX7*), Congenital disorder of glycosylation *(PMM2-CDG*), Alpha-1 antitrypsin deficiency (*SERPINA1*), Mucopolysaccharidosis type IIIA (*SGSH*), Pendred syndrome (*SLC26A4*), Spinal muscular atrophy (*SMN1*), Lamellar ichthyosis (*TGM1*), Neuronal ceroid-lipofuscinosis (*TPP1*)

8) Examined genes: *SMN1, SMN2, BRCA 1, BRCA2, CHEK2, NF1*

9) Implemented procedures for PGT-M (monogenic diseases):
21-hydroxylase deficiency (adrenogenital syndrome, *CYP21A2*), Adrenoleukodystrophy (*ABCD1*), Aicardi-Goutiere syndrome, Achondroplasia (*FGFR3*), Polycystic Kidney Disease *(ADPKD*), Hereditary Breast and Ovarian Syndrome (*BRCA1, BRCA2*), CADASIL (Cerebral Autosomal Dominant Arteriopathy with Subcortical Infarcts and Leukoencephalopathy) (*NOTCH3*) Cystic Fibrosis (*CFTR*), Charcot-Marie-Tooth (*PMP22, CMTX1, GJB1 for connexin 32*), Nonsyndromic Deafness (*GJB2* for connexin 26), Duchenne Muscular Dystrophy (*DMD*), Ehlers-Danlos Syndrome (*COL3A1*), Ectrodactyly (*TP63*), FRA11B, FRAXA (*FMR1*), FSHD (subtelomeric region 4q35.), Hemophilia A (*F8*) Hemophilia B (*F9*), Incontinentia pigmenti (*IKGKB*, formerly *NEMO*), Huntington's chorea (*HTT,IT15*), Hyperekplexia, Periodic hypokalemic palsy (*CACNA1S*), Ichthyosis (*KRT10*), Jeune syndrome, Krabbe's disease (*GALC*), LIG4 syndrome (*LIG4*), Lynch syndrome (*MLH1*), Marfan syndrome (*FBN1*), Mucopolysaccharidosis type IIIA (*SGSH*), Muscle-eye-brain syndrome (*POMGnT1*), Myotonic dystrophy (*DMPK1*), Neurofibromatosis (*NF1, NF2*), Prader-Willi syndrome (15q11. 2), Retinitis pigmentosa (*PRPF31/RP11*), Rhabdoid Tumor Predisposition Syndrome (*SMARCA4/BRG1*), Sandhoff disease (*HEXB*), Smith-Lemli-Opitz syndrome (SLOS, *DHCR7* gene), Spinal muscular atrophy (*SMN1*), Spinocerebellar ataxia, Testicular feminization syndrome (*AR*), Treacher-Collins syndrome (*TCOF1*), Tuberous sclerosis, Von Hippel Lindau syndrome (*VHL*), Zellweger syndrome, (*PEX13*)

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