

**The Appendix is an integral part of
Certificate of Accreditation No. 131/2018 of 15/03/2018**

Accredited entity according to ČSN EN ISO 15189:2013:

Genetika Plzeň, s.r.o.

Genetics Laboratory

Parková 1254/11a, 326 00 Plzeň-Černice

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 Molecular Genetics Department Manager.

Examinations:

Ordinal number	Examination procedure name	Examination procedure identification	Examined object
813 - Allergology and Immunology Laboratory			
1.	Determination of cardiolipin IgG and IgM antibodies by ELISA method	SOP 31	Serum
2.	Determination of Annexin V IgG and IgM antibodies by ELISA method	SOP 32	Serum
3.	Determination of beta2-Glycoprotein I IgA and IgG antibodies by ELISA method	SOP 33	Serum
4.	Determination of IgA and IgG antisperm antibodies in ejaculate by agglutination method – direct and indirect MAR test	SOP 34	Ejaculate, serum, ovulatory secretion
5.	Determination of sperm acrosomes by Lectin from Pisum Sativum labelled by FITC by immunofluorescence method	SOP 37	Ejaculate
6.	Detection of anti-spermatozoa antibodies in serum by agglutination method	SOP 38	Serum
7.	Determination of antizonal antibodies by hemagglutination test	SOP 39	Serum, peritoneal and follicular fluid
816 - Medical Genetics Laboratory			
1.	Cytogenetic examination of caryotype from human cells	SOP 01	Fetal and peripheral blood, amniotic fluid, chorionic and aborted tissue



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Ordinal number	Examination procedure name	Examination procedure identification	Examined object
2.	Detection of 35delG mutation in gene for Connexin 26 by allele-specific PCR	SOP 08	Peripheral blood, buccal smear, amniotic fluid (native and cultured)
3.	Detection of Y chromosome microdeletions by multiplex PCR analysis	SOP 09	Peripheral blood and buccal smear
4.	Determination of parentage by the analysis of STR markers by multiplex PCR method using the Identifiler commercial set	SOP 10	Peripheral blood and buccal smear
5.	Examination of chromosome aneuploidies, microdeletions and structural changes by fluorescence in-situ hybridization (FISH) method	SOP 11	Peripheral blood, amniotic fluid, aborted tissue, blastomere
6.	Examination of 13, 18, 21, X and Y chromosome aneuploidies by STR analysis by QF PCR method (Amnio QF PCR)	SOP 12	Peripheral blood, amniotic fluid, aborted tissue, buccal smear, chorionic villi
7.	Detection of HLA DQ2 and DQ8 allele groups for coeliac disease predisposition by allele-specific PCR	SOP 14	Peripheral blood, buccal smear
8.	Determination of mutations responsible for inherent thrombophilic states ¹⁾ by Real Time PCR method	SOP 16	Peripheral blood, buccal smear
9.	Examination of CGG repetition expansion in FMR1 gene by PCR method with subsequent fragment analysis	SOP 17	Peripheral blood, buccal smear, chorionic villi, aborted tissue, amniotic fluid (native and cultured)

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Ordinal number	Examination procedure name	Examination procedure identification	Examined object
10.	Mutation analysis/gene screening ²⁾ by Sanger sequencing method	SOP 18	Peripheral blood, buccal smear, chorionic villi, aborted tissue, amniotic fluid (native and cultured)
11.	Examination of CFTR gene mutations by multiplex PCR method with subsequent fragment analysis	SOP 19	Peripheral blood, buccal smear, chorionic villi, aborted tissue, amniotic fluid (native and cultured)
12.	Examination of copy number variations CNV by comparative genomic hybridization on chip (ARRAY CGH)	SOP 20	Peripheral and fetal blood, buccal smear, amniotic fluid, chorionic and aborted tissue
13.	Reserved		
14.	Preimplantation genetic testing of aneuploidies (PGT-A) by massive parallel sequencing method (platform Miseq, Illumina)	SOP 22	Embryo trophectoderm cells
15.	Gene mutation analysis by massive parallel sequencing method (platform Miseq, Illumina) ²⁾	SOP 23	Peripheral blood
16.	Determination of intragenic alterations of genes by MLPA method ²⁾³⁾	SOP 24	Peripheral blood, buccal smear, amniotic fluid, chorionic villi
Laboratory examination for IVF			
1.	Examination of spermogram by microscopic technique	SOP 03	Ejaculate

1) genes: factor V, factor II, MTHFR, PAI1

2) genes: ATM, APC, BARD1, BRCA1, BRCA2, BRIP1, CDH1, CHEK2, EPCAM, MLH1, MSH2, MSH6, MUTYH, NBN, PALB2, PMS2, PTEN, RAD50, RAD51C, RAD51D, STK11, TP53

3) genes: SMN1, SMN2



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Explanations and abbreviations:

ARRAY CGH Comparative Genome Hybridization on a chip
CGG Repetitions of nucleotides (C) and guanine (G)
CNV Copy Number Variation

PCR Polymerase Chain Reaction
STR Short Tandem Repeats
QF PCR Quantitative Fluorescent Polymerase Chain Reaction
MLPA Multiplex Ligation-Dependent Probe Amplification

Annex:

Flexible scope of accreditation

Examination procedure ordinal numbers
10, 15, 16

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.

