The Appendix is an integral part of
Certificate of Accreditation No. 509/2022 of 27/10/2022

Accredited entity according to ČSN EN ISO 15189:2013:

GENvia, s.r.o.

Laboratory of Medical Genetics
Sýkovecká 276/54, 198 00 Praha 9 – Kyje

The Laboratory has a flexible scope of accreditation permitted as detailed in the Annex. Updated list of activities provided within the required flexible scope of accreditation is available on the laboratory website www.genvia.cz.

Examinations:

Ordinal number	Examination procedure name	Examination procedure identification	Examined object
802 - Medical microbiology			
1.	Examination for the detection of SARS-CoV-2 virus RNA by real-time RT PCR method	SOP26	Isolated RNA**
816 - Medical Genetics Laboratory			
1.	Cytogenetic determination of karyotype from amniotic fluid	SOP1	Amniotic fluid
2.	Cytogenetic determination of karyotype from fetal and peripheral blood	SOP2	Fetal blood, peripheral blood
3.	Cytogenetic determination of karyotype from chorion and aborted fetal tissue	SOP3	Chorium, aborted tissue
4.	Examination of aneuploidies, microdeletions and chromosomal aberrations of cultured and native cells from blood, amniotic fluid, tissue and blastomeres by FISH analysis	SOP4	Blood, amniotic fluid, tissue, blastomere
5.	Detection of CFTR gene mutations (cystic fibrosis) using PCR with subsequent fragment analysis[1]	SOP11	Isolated DNA*
6.	HLA typing by allele-specific PCR primer method[2]	SOP25	Isolated DNA*
7.	Gene mutation analysis by massive parallel sequencing method[3]	SOP24	Isolated DNA*
8.	Determination of blood-relationship using STR markers by PCR method with subsequent fragment analysis[4]	SOP15-01	Isolated DNA*

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Ordinal number	Examination procedure name	Examination procedure identification	Examined object
9.	Detection of AZFa, AZFb and AZFc microdeletions of the chromosome Y by PCR method with subsequent fragment analysis	SOP12-02	Isolated DNA*
10.	Detection of thrombophilic mutations: Factor V Leiden, Factor II Prothrombin, MTHFR C677T and MTHFR A1298C and PAI-1 4G/5G by real-time PCR method	SOP13-03	Isolated DNA*
11.	Molecular genetic examination of aneuploidies by QF PCR method[7]	SOP14-02	Isolated DNA*
12.	Detection of UGT1A1∗28 polymorphism conditioning the formation of Gilbert's syndrome by fluorescent PCR and fragment analysis	SOP16-01	Isolated DNA*
13.	Examination of deletions and duplications of all chromosomes by microarray CGH method	SOP20-01	Isolated DNA*
14.	Examination of intragenic alterations by MLPA method[5]	SOP21	Isolated DNA*
15.	Examination of fragile X chromosome syndrome by PCR and Repeat Primed PCR methods	SOP22	Isolated DNA*
16.	Examination of genes by Sanger sequencing method[6]	SOP23	Isolated DNA*

Annex:

Flexible scope of accreditation

Examination procedure ordinal numbers
816: 5, 6, 7, 8, 11, 14, 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.

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Explanatory notes:

[1]Mutations detected by Elucigene CF-EU2 kit: R347H, R347P, 2789+5 G>A, 3120+1 G>A, 711+1 G>T, R334W, I507del, F508del, 3849+10kb C>T, 1677delTA, 1078delT, V520F, L206W, W1282X, R560T, 2347delG, Q890X, R553X, G551D, S549R, S549N, M1101K, G542X, 3905insT, Y1092X, S1251N, 444delA, 1811+1.6kb A>G, 1717-1 G>A, R117H, R117C, N1303K, Y122X, 394delTT, G85E, R1066C, 1898+1 G>A, W846X, 2184delA, D1152H, CFTRdele2_3(21kb), P67L, 2143delT, E60X, 3659delC, 3272-26 A>G, 621+1G>T, A455E, R1162X, R1158X.

Mutations detected by Devyser CFTR core kit: CFTRdele2,3, E60X, P67L, G85E, 394delTT, 444delA, R117C, R117H, Y122X, 621+1G>T, 711+1G>T, L206W, 1078delT, R334W, R347P, R347H, A455E, I507del, F508del, 1677delTA, V520F, 1717-1G>A, G542X, S549R(T>G), S549N, G551D, R553X, R560T, 1811+1.6kbA>G, 1898+1G>A, 2143delT, 2184delA, 2347delG, W846X, 2789+5G>A, Q890X, 3120+1G>A, 3272-26A>G, R1066C, Y1092X(C>A), M1101K, D1152H, R1158X, R1162X, 3659delC, 3849+10kbC>T, S1251N, 3905insT, W1282X, N1303K

[2]Alleles detected by Olerup SSP® kit: DQA1*02,*05;DQB1*02,*03:02
Alleles detected by Olerup SSP® kit: HLA-B*27

[3]Examination of genes: BRCA1, BRCA2, COL1A1, COL1A2 and GENvia panel genes: APC, ATM, BAP1, BARD1, BLM, BMPR1A, BRCA1, BRCA2, BRIP1, CDH1, CDKN2A, EPCAM, FANCC, FANCM, HOXB13, CHEK2, KIT, MLH1, MLH3, MRE11A, MSH2, MSH6, MUTYH, NBN, PALB2, PIK3CA, PMS2, POLD1, POLE, PRSS1, PTEN, RAD51C, RAD51D, RECQL, RECQL4, RINT1, SLX4, SMAD4, SMARCA4, STK11, TP53, VLH a XRCC2 and AR panel genes: AR, INSL3, INSL3R, SRY, SOX9, DHH, NR5A1, MAP3K1, ZFPM2 and NR2F2.

[4]Detection of STR markers by AmpFlSTR® Identifiler®kit

[5]Exaamination of genes: BRCA1, COL1A1, SMN1 a SMN2, CFTR, CHEK2, DHCR7, MLH1, MSH2, MSH6, MUTYH, PMS2, STK11

[6]Examination of genes: BRCA1, BRCA2, COL1A1, COL1A2, GJB2 (connexin26), DHCR7 (SLOS) and GENvia panel genes: APC, ATM, BAP1, BARD1, BLM, BMPR1A, BRCA1, BRCA2, BRIP1, CDH1, CDKN2A, EPCAM, FANCC, FANCM, HOXB13, CHEK2, KIT, MLH1, MLH3, MRE11A, MSH2, MSH6, MUTYH, NBN, PALB2, PIK3CA, PMS2, POLD1, POLE, PRSS1, PTEN, RAD51C, RAD51D, RECQL, RECQL4, RINT1, SLX4, SMAD4, SMARCA4, STK11, TP53, VLH a XRCC2

[7]Aneuploidies detected by Devyser Compact kit: 13,18,21,X,Y
Aneuploidies detected by Devyser Extend kit: 13,15,16,18,21,22,X,Y

*DNA isolated from blood, buccal smear, chorionic villi, amniotic fluid, aborted tissues
**RNA isolated from nasopharyngeal swab, oropharyngeal swab, nasal swab, saliva, sputum, sample obtained from gargling, tracheal aspirate, BAL (bronchoalveolar lavage)