



List of activities within the flexible scope of accreditation

Accredited Body: Cytogenetická laboratoř Brno, s.r.o.
CAB Name: Cytogenetic Laboratory Brno
CAB Number: 8067
Certificate of Accreditation No. 455/2024
Field of Accreditation: Medical Laboratory - ČSN EN ISO 15189 ed. 3:2023
Updated: 24.03.2026

Examinations:

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of method procedure/ equipment	Examined material	Degrees of freedom ¹
816 – Medical Genetics Laboratory					
1.	Examination of constitutional karyotype	Conventional cytogenetic analysis	SOP-C1, Issue 4 SlideExpress 2	Amniotic fluid, peripheral blood, umbilical blood, chorionic villi, tissue of aborted fetus, cultivated tissue culture	A
2.	Examination of germline genome variants	PCR-fragment analysis	SOP-M1, Issue 2; I-15, 18/01/2023; I-19, 23.07.2025; I-28, 15/05/2023 ABI 3130 Genetic Analyzer, Applied Biosystems, SeqStudio	DNA, amniotic fluid, chorionic villi, tissue of aborted fetus, umbilical blood, peripheral blood, buccal swab	A,B,C,D
3.	Examination of germline genome variants	PCR-fragment analysis	SOP-M2, Issue 2; I-19, 23.07.2025 SureScanDx Microarray Scanner Agilent Technologies, 8x60K	DNA, amniotic fluid, chorionic villi, tissue of aborted fetus, umbilical blood, peripheral blood, buccal swab	A,B,C,D
4.	Examination of germline genome variants	NGS-MPS	SOP-M3, Issue 6; I-19, 23.07.2025; I-28, 15.05.2023 I-36, 01.02.2024 I-40, 09.01.2024 Miseq Illumina, NextSeq Illumina	DNA, amniotic fluid, chorionic villi, tissue of aborted fetus, umbilical blood, peripheral blood, buccal swab	A,B,C,D

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Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of method procedure/ equipment	Examined material	Degrees of freedom ¹
5.	Examination of germline genome variants	HRM	SOP-M4, Issue 3; I-14, 06/01/2016; I-19, 23.07.2025; I-28, 15/05/2023 LightScanner 32, Idaho Technology Inc.	DNA, peripheral blood, buccal smear	A,B,C,D
6.	Examination of germline genome variants	MLPA	SOP-M6, Issue 2; I-19, 23.07.2025 ABI 3130 Genetic Analyzer, Applied Biosystems	DNA, amniotic fluid, chorionic villi, tissue of aborted fetus, umbilical blood, peripheral blood, buccal swab	A,B,C,D
7.	Examination of unbalanced chromosomal aberrations	Comparative genomic hybridization on a biochip	SOP-M7, Issue 4; I-19, 23.07.2025; I-23, 09/11/2016; I-28, 15/05/2023; I-31, 25/04/2023 SureScan Dx Microarray Scanner Agilent Technologies, 8x60K	DNA, amniotic fluid, chorionic villi, tissue of aborted fetus, umbilical blood, peripheral blood, buccal swab	A,B,C,D
8.	Non-invasive prenatal test (NIPT) of genomic variants	NGS-MPS	SOP-M8, Issue 5; I-17, 27/01/2023 I-19, 23/07/2025 Miseq Illumina, NextSeq Illumina	Free fetal DNA, maternal peripheral blood, maternal peripheral blood plasma	A,B,C,D
9.	Examination of germline genome variants	dTP-PCR	SOP-M17, Issue 4; I-19, 23.07.2025; I-23, 09/11/2016; I-28, 15/05/2023 ABI 3130 Genetic Analyzer, Applied Biosystems	DNA, amniotic fluid, chorionic villi, tissue of aborted fetus, umbilical blood, peripheral blood, buccal swab	A,B,C,D
10.	Examination of germline genome variants	RealTime PCR	SOP-M20, Issue 2; I-19, 15/06/2022; I-28, 15/05/2023 Bio-Rad CFX 96	DNA, peripheral blood, buccal swab	A,B,C,D

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Specification of the scope of accreditation:

Field Nr. / Ordinal Number	Detailed information on activities within the scope of accreditation
816/2	<p>QF-PCR method using diagnostic kits:</p> <ul style="list-style-type: none"> • Devyser Resolution 21 v2: for the diagnosis of chromosome 21 aneuploidy • Devyser Complete v2: for the detection of aneuploidies of chromosomes 13, 18, 21, X and Y • Devyser Extend M1 v2: for the detection of aneuploidies of chromosomes 15, 16 and 22 • Devyser Resolution XY v2: for the detection of aneuploidies of chromosomes X and Y
816/3	<p>Testing for the most common mutations in the <i>CFTR</i> gene by ARMS method:</p> <ul style="list-style-type: none"> • Devyser CFTR Core / Devyser CFTR Italia v2 (67M): Traditional nomenclature: <i>F508del</i>, <i>CFTRdele2,3(21kb)</i>, <i>G551D</i>, <i>N1303K</i>, <i>G542X</i>, <i>1898+1 G>A</i>, <i>2143delT</i>, <i>R347P</i>, <i>W1282X</i>, <i>1717-1G>A</i>, <i>R1162X</i>, <i>3849+10kb C>T</i>, <i>2184insA</i>, <i>G85E</i>, <i>621+1G>T</i>, <i>R334W</i>, <i>R553X</i>, <i>2183AA>G</i>, <i>2789+5G>A</i> <i>I336K</i>, <i>CFTR-dele2</i>, <i>Q552X</i>, <i>D1152H</i>, <i>R1158X</i>, <i>S549R(A>C)</i>, <i>3272-26A>G</i>, <i>CFTRdele22,23</i>, <i>D110H</i>, <i>3659delC</i>, <i>Q39X</i>, <i>R117C</i>, <i>711+1G>T</i>, <i>R347H</i>, <i>I507del</i>, <i>E585X</i>, <i>2184delA</i>, <i>R1066C</i>, <i>R117H</i>, <i>1078delT</i>, <i>1677delTA</i>, <i>R650T</i>, <i>3120+1G>A</i>, <i>Y1092X(C>A)</i>, <i>T388I</i>, <i>L1077P</i>, <i>L1065P</i>, <i>M1V</i>, <i>P5L</i>, <i>Dele17a_18</i>, <i>852del22</i>, <i>CFTRdele1</i>, <i>D110E</i>, <i>R1066H</i>, <i>G1244E</i>, <i>c.1584+18672A>G</i>, <i>1259insA</i>, <i>711+5G>A</i>, <i>R352Q</i>, <i>G178R</i>, <i>D579G</i>, <i>1898+3A>G</i>, <i>4382delA</i>, <i>4016insT</i>, <i>Dele14b_17b</i>, <i>Dele2ins182</i>, <i>Dele22_24</i>, <i>G1349D</i> HGVS nomenclature: <i>c.1521_1523delCTT</i>, <i>c.54-5940_273+10250del21080</i>, <i>c.1652G>A</i>, <i>c.3909C>G</i>, <i>c.1624G>T</i>, <i>c.1766+1G>A</i>, <i>c.2012delT</i>, <i>c.1040G>C</i>, <i>c.3846G>A</i>, <i>c.1585-1G>A</i>, <i>c.3484C>T</i>, <i>c.3718-2477C>T</i>, <i>c.2052_2053insA</i>, <i>c.254G>A</i>, <i>c.489+1G>T</i>, <i>c.1000C>T</i>, <i>c.1657C>T</i>, <i>c.2051_2052delAAinsG</i>, <i>c.2657+5G>A</i>, <i>c.1007T>A</i>, <i>c.54-1161_164+1603del2875</i>, <i>c.1654C>T</i>, <i>c.3454G>C</i>, <i>c.3472C>T</i>, <i>c.1645A>C</i>, <i>c.3140-26A>G</i>, <i>c.3964-78_4242+577del</i>, <i>c.328G>C</i>, <i>c.3528delC</i>, <i>c.115C>T</i>, <i>c.349C>T</i>, <i>c.579+1G>T</i>, <i>c.1040G>A</i>, <i>c.1519_1521delATC</i>, <i>c.1753G>T</i>, <i>c.2052delA</i>, <i>c.3196C>T</i>, <i>c.350G>A</i>, <i>c.948delT</i>, <i>c.1545_1546delTA</i>, <i>c.1679G>C</i>, <i>c.2988+1G>A</i>, <i>c.3276C>A</i>, <i>c.1013C>T</i>, <i>c.3230T>C</i>, <i>c.3194T>C</i>, <i>c.1A>G</i>, <i>c.14C>T</i>, <i>c.2988+1173_3468+2111del</i>, <i>c.720_741delAGGGAGAATGATGATGAAGTAC</i>, <i>c.4+53+69delins299</i>, <i>c.330C>A</i>, <i>c.3197G>A</i>, <i>c.3731G>A</i>, <i>c.1585-9412A>G(c.1584+18672A>G)</i>, <i>c.1127_1128insA</i>, <i>c.579+5G>A</i>, <i>c.1055G>A</i>, <i>c.532G>A</i>, <i>c.1736A>G</i>, <i>c.1753G>T</i>, <i>c.4251delA</i>, <i>c.3884_3885insT</i>, <i>c.2620-674_3367+198del</i>, <i>c.54-5811_164+2186del8108ins182</i>, <i>c.3964-3890_3143delinsTAACT</i>, <i>c.4046G>A</i> • Devyser CFTR 68: Traditional nomenclature: <i>711+1G>T</i>, <i>2043delG</i>, <i>1677delTA</i>, <i>W1282X</i>, <i>R1283M</i>, <i>K710X</i>, <i>3849+10kbC>T</i>, <i>2789+5G>A</i>, <i>M1101K</i>, <i>G85E</i>, <i>3905insT</i>, <i>1525-1G>A</i>, <i>2184delA</i>, <i>3659delC</i>, <i>N1303K</i>, <i>2184insA</i>, <i>1812-1G->A</i>, <i>CFTRdele2,3</i>, <i>2143delT</i>, <i>Y569D</i>, <i>R1162X</i>, <i>A561E</i>, <i>S1251N</i>, <i>P67L</i>, <i>R1158X</i>, <i>1609delCA</i>, <i>Q493X</i>, <i>E60X</i>, <i>1898+1G>A</i>, <i>1898+5G>T</i>, <i>I507del</i>, <i>F508del</i>, <i>V520F</i>, <i>394delTT</i>, <i>D1152H</i>, <i>V232D</i>, <i>L218X</i>, <i>621+2T>C</i>, <i>1717-1G>A</i>, <i>L206W</i>, <i>E92X</i>, <i>3120+1G>A</i>, <i>G542X</i>, <i>S549N</i>, <i>G551D</i>, <i>712-1G>T</i>, <i>R553X</i>, <i>3272-26A>G</i>, <i>R560T</i>, <i>2183AA>G</i>, <i>R117H</i>, <i>R117C</i>, <i>1811+1.6kbA>G</i>, <i>2869insG</i>, <i>Y122X</i>, <i>Q890X</i>, <i>R1066C</i>, <i>R347H</i>, <i>R347P</i>, <i>1161delC</i>, <i>1154ins TC</i>, <i>E92K</i>, <i>I336K</i>, <i>R334W</i>, <i>Y1092X (C>A)</i>, <i>621+1G>T</i>, <i>1078delT</i>, <i>A455E</i> HGVS nomenclature: <i>c.579+1G>T</i>, <i>c.1911delG</i>, <i>c.1545_1546delTA</i>, <i>c.3846G>A</i>, <i>c.3848G>T</i>, <i>c.2128A>T</i>, <i>c.3718-2477C>T</i>, <i>c.1519_1523ATCTT</i>, <i>c.2657+5G>A</i>, <i>c.3302T>A</i>, <i>c.254G>A</i>, <i>c.3773_3774insT</i>, <i>c.1393-1G->A</i>, <i>c.2052delA</i>, <i>c.3528delC</i>, <i>c.3909C>G</i>, <i>c.2052_2053insA</i>, <i>c.1680-1G>A</i>, <i>c.54-5940_273+10250del21kbc.2012delT</i>, <i>c.1705T>G</i>, <i>c.3484C>T</i>, <i>c.1682C>A</i>, <i>c.3752G>A</i>, <i>c.200C>T</i>, <i>c.3472C>T</i>, <i>c.1477_1478delCA</i>, <i>c.1477C>T</i>, <i>c.178G>T</i>, <i>c.1766+1G>A</i>, <i>c.1766+5G>T</i>, <i>c.1519_1521delATC</i>, <i>c.1521_1523delCTT</i>, <i>c.1558G>T</i>, <i>c.262_263delTT</i>, <i>c.3454G>C</i>, <i>c.695T>A</i>, <i>c.653T>A</i>, <i>c.489+2T>C</i>, <i>c.1585-1G>A</i>, <i>c.617T>G</i>, <i>c.274G>T</i>, <i>c.2988+1G>A</i>, <i>c.1624G>T</i>, <i>c.1646G>A</i>, <i>c.1652G>A</i>, <i>c.580-1G>T</i>, <i>c.1657C>T</i>, <i>c.3140-26A>G</i>, <i>c.1679G>C</i>, <i>c.2051_2052delAAinsG</i>, <i>c.350G>A</i>, <i>c.349C>T</i>, <i>c.1680-886A>G</i>, <i>c.2737_2738insG</i>, <i>c.366T>A</i>, <i>c.2668C>T</i>, <i>c.3196C>T</i>, <i>c.1040G>A</i>, <i>c.1040G>C</i>, <i>c.1029delC</i>, <i>c.1022_1023insTC</i>, <i>c.274G>A</i>, <i>c.1007T>A</i>, <i>c.1000C>T</i>, <i>c.3276C>A</i>, <i>c.489+1G>T</i>, <i>c.948delT</i>, <i>c.1364C>A</i>
816/4	<ul style="list-style-type: none"> • NGS Cardio v6 - list of genes (https://www.cytogenetika.cz/sluzby/dedicna-onemocneni-srdce) <i>ADAMTS2</i>, <i>ALG10B</i>, <i>ALMS1</i>, <i>A2ML1</i>, <i>ALPK3</i>, <i>ABCC9</i>, <i>ACTA1</i>, <i>ACTA2</i>, <i>ACTC1</i>, <i>ACTN2</i>, <i>ACVR2B</i>, <i>AKAP9</i>, <i>ANK2</i>, <i>ANKRD1</i>, <i>B2M</i>, <i>B4GALT7</i>, <i>BAG3</i>, <i>BGN</i>, <i>BRAF</i>, <i>CACNA1C</i>, <i>CACNA2D1</i>, <i>CACNB2</i>, <i>CALM1</i>, <i>CALM2</i>, <i>CALM3</i>, <i>CALR3</i>, <i>CASQ2</i>, <i>CAV3</i>, <i>CBL</i>, <i>CCDC11</i>, <i>CFC1</i>, <i>CFHR5</i>, <i>CHD7</i>, <i>CITED2</i>, <i>COL1A1</i>, <i>COL1A2</i>, <i>COL3A1</i>, <i>COL4A3</i>, <i>COL4A4</i>, <i>COL4A5</i>, <i>COL5A1</i>, <i>COL5A2</i>, <i>CRELD1</i>, <i>CRYAB</i>, <i>CSRP3</i>, <i>CTF1</i>, <i>CTNNA3</i>, <i>DCHS1</i>, <i>DES</i>,

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	<p><i>DMD, DOLK, DPP6, DSC2, DSE, DSG2, DSP, DTNA, EFEMP2, ELN, EMD, EVC, EVC2, FBN1, FBN2, FHL1, FHL2, FHOD3, FLNA, FKBP14, FKTN, FLNC, FOG2/ZFPM2, FOXE, FOXH1, FXN, GAA, GATA4, GATA5, GATA6, GATAD1, GDF1, GJA1, GJA5, GLA, GPD1L, GSN, HAND1, HAND2, HCN4, HFE, HEY2, HRAS, JAG1, JUP, JPH2, KAT6b, KCNA5, KCND2, KCND3, KCNE1, KCNE2, KCNE3, KCNE5, KCNH2, KCNJ2, KCNJ5, KCNJ8, KCNQ1, KLF10, KMT2D, KRAS, LAMA2, LAMA4, LAMP2, LDB3, LEFTY2, LMNA, LOX, LZTR1, MAP2K2, MAT2A, MED12, MED13L, MEK1, MFAP5, MIB1, MIB2, MOG1, MRAZ, MYBPC3, MYH6, MYH7, MYH9, MYH11, MYL2, MYL3, MYLK, MYLK2, MYLK3, MYOC, MYOM, MYOZ2, MYPN, NEBL, NEXN, NF1, NF2, NKX2-5, NKX2-6, NODAL, NR2F2, NOS1AP, NOTCH1, NOTCH2, NPPA, NRAS, NUP155, OBSCN, PDLIM3, PKP2, PLOD1, PLN, PPCS, PPP1CB, PPP1R13L, PRDM16, PRKAG2, PRKG1, PSEN2, PTPN11, RAF1, RASA1, RASA2, RBM8A, RBM10, RBM20, RIT1, RRAS, RYR1, RYR2, SALL4, SDHA, SEMA3E, SCN10A, SCN1B, SCN2B, SCN3B, SCN4B, SCN5A, SGCD, SHOC2, SHROOM, SKI, SLC2A10, SLMAP, SMAD2, SMAD3, SMAD4, SMAD6, SMARCB1, SNTA1, SCO2, SOS1, SOS2, SPRED1, SYNE2, TAB2, TAZ, TBX1, TBX3, TBX5, TBX20, TCAP, TECRL, TFAP2B, TGFBR1, TGFBR2, TGFB2, TGFB3, TGFBR3, TLL1, TMEM43, TMPO, TNN3, TNN3K, TNNC1, TNNT2, TNXB, TPM1, TRDN, TRIM54, TRIM63, TRPM4, TTN, TTR, TXNRD2, VCL, ZIC3 / MT-TL1-rs199474657</i></p> <ul style="list-style-type: none"> • NGS Rasopathy, a list of genes (https://www.cytogenetika.cz/sluzby/ngs-panel-rasopatie) <p><i>PTPN11, SOS1, RAF1, RIT1, BRAF, KRAS, NRAS, MAP2K1, RRAS, CBL, SHOC2, A2ML1, LZTR1, RASA2, SOS2, MAP2K2, HRAS, SPRED1, NF1, NF2, PPP1CB, KAT6b, MRAS, RASA1, SMARCB1</i></p> <ul style="list-style-type: none"> • Heredity - clinical exome (<i>G:\I_Molekularni laborator\I_VYSETRENI\HEREDITYPANEL\Info\KAPA_Heredity KAPA\HyperCapHeredity_gene_list</i>) <p>A list of 3332 genes can be provided upon request by the referring physician.</p> <ul style="list-style-type: none"> • WES (Twist 2.0) Twist Bioscience, wholeexom(36,5Mb)(https://www.cytogenetika.cz/sluzby/WES)
816/5	<p>Examination of 3 thrombophilic mutations (HRM):</p> <ul style="list-style-type: none"> - mutations in the gene for Factor V (1691 G>A) - mutations in the gene for Factor II (20210G>A) - mutations in the gene for MTHFR (677 C>T)
816/6	<p>Selected diagnoses:</p> <ul style="list-style-type: none"> • Spinal muscular atrophy – copy numbers of exons 7 and 8 of genes: <i>SMN1 and SMN2</i> • Syndrom DiGeorge – gene copy numbers: <i>PPIL2, SLC25A18, DGCR8, HIRA, SNRPD3, TBX1, MICAL3, CLTCL1, CLDN5, ZNF74, GP1BB, GNAZ, SMARCB1, USP18, TXNRD2, TBX1, RSPH14, KLHL22, TOP3B, HIC2, MED15, IL17RA, RAB36, BID, SNAP29, SMARCB1, LZTR1, RSPH14, CDC45</i> in 22q11 region • NF1 – copy numbers of exons 1 to 58 of the <i>NF1</i> gene
816/7	<p>Format 8x60K, AMADID (18,851 probes in ISCA regions + 40,208 backbone probes) practical median probe spacing is approx. 100 kb (with higher resolution in ISCA regions)</p>
816/8	<ul style="list-style-type: none"> • Chromosomes 16, 18, 21, X, Y Trisomy test • Trisomy XY test • Trisomy test + • Trisomy Complete
816/9	<p>Expansion of CGG repeat in <i>FMRI</i> gene</p>
816/10	<p>Examination of 3 thrombophilic mutations (real-time PCR)</p> <ul style="list-style-type: none"> - mutations in the gene for Factor V (1691 G>A) - mutations in the gene for Factor II (20210G>A) - mutations in the gene for MTHFR (677 C>T)



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Explanatory notes:

¹ Established degrees of freedom according to MPA 00-09-...:

A – Flexibility concerning the documented examination/ sample collection procedure

B – Flexibility concerning the technique

C – Flexibility concerning the analytes / parameters

D – Flexibility concerning the examined material

If no degree of freedom is specified, the laboratory cannot apply a flexible approach to the scope of accreditation for this examination.

MLPA	Multiplex Ligation-Dependent Probe Amplification
NGS-MPS	Massive parallel sequencing (Next Generation Sequencing – NGS)
HRM	High Resolution Melting Curve Analysis
QF PCR	Quantitative Fluorescence Polymerase Chain Reaction
ARMS	Allele-specific amplification
Real-Time PCR	Real-Time Polymerase Chain Reaction
dTP-dCR	Direct Triplet-Primed PCR method
WES	Whole Exome Sequencing