

List of activities within the flexible scope of accreditation

Accredited Body: CENTRUM LÉKAŘSKÉ GENETIKY s.r.o.
CAB Name: Center for Medical Genetics, Ltd. - Laboratory
CAB Number: 8046
Certificate of Accreditation No.: 150/2023
Field of Accreditation: Medical laboratory - ČSN EN ISO 15189:2013
Updated: 12/05/2025

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	SP-CG-01, ed. 12, 12.5.2025; MP-CG-03, ed. 2, 12.5.2025; MP-CG-02, ed. 1, 9.2.2019; N-CG-05, ed. 1, 9.2.2019 change 1, 30.4.2025; N-CG-06, ed. 1, 9.2.2019; N-CG-07, ed. 1, 9.2.2019; N-CG-08, ed. 1, 9.2.2019, change 1, 2.5.2025;	Amniotic fluid, blood, tissue	A, B, D
2.	Examination of constitutional chromosomal aberrations	FISH	SP-CG-02, ed. 7, 12.5.2025; N-CG-04, ed. 4, 2.5.2025; N-CG-05, ed. 1, 9.2.2019 change 1, 30.4.2025; N-CG-10, ed. 1, 9.2.2019, change 1, 2.5.2025; N-CG-11, ed. 1, 9.2.2019;	Blood, amniotic fluid, tissue, urine	A, B, D
3.	Examination of germline genome variants	PCR-RFLP	SP-MG-01, ed. 6, 18.1.2019; MP-MG-03, ed.10, 31.1.2022; N-MG-04, ed. 3, 8.3.2019	Blood, buccal smear	A, B, C, D

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4.	Examination of germline genome variants	Multiplex PCR	SP-MG-02, ed. 6, 18.1.2019; MP-MG-03, ed.10, 31.1.2022; N-MG-04, ed. 3, 8.3.2019	Blood, buccal smear	A, B, C, D
5.	Examination of germline genome variants	Reverse hybridization	SP-MG-03, ed. 9, 19.5.2020; MP-MG-03, ed.10, 31.1.2022;	Blood, amniotic fluid, buccal smear	A, B, C, D
6.	Examination of germline genome variants	PCR – capillary electrophoresis	SP-MG-04, ed. 10, 30.6.2020; MP-MG-03, ed.10, 31.1.2022; ABI PRISM 3130	Blood, amniotic fluid, chorionic villi, buccal smear	A, B, C, D
7.	Examination of germline genome variants	Real-Time PCR	SP-MG-06, ed. 7, 18.1.2019; MP-MG-03, ed.10, 31.1.2022; Rotor-Gene 6000	Blood, buccal smear	A, B, C, D
8.	Examination of germline genome variants	Sanger sequencing	SP-MG-08, ed. 6, 3.1.2020; MP-MG-03, ed.10, 31.1.2022; MP-MG-07, ed. 11, 23.1.2025; MP-MG-08, ed. 3, 17.1.2019; ABI PRISM 3130	Blood	A, B, C, D

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9.	Examination of germline genome variants	NGS	SP-MG-09, ed. 14, 23.1.2025; MP-MG-02, ed. 9, 10.6.2020; MP-MG-03, ed.10, 31.1.2022; MP-MG-07, ed. 11, 23.1.2025; MP-MG-09, ed. 9, 23.1.2025; MP-MG-11, ed. 11, 23.1.2025; MP-MG-12, ed. 10, 3.7.2024; MP-MG-20, ed.2, 21.8.2023, change 1, 8.12.2023; MiSeq, NextSeq 500/550	Blood	A, B, C, D
10.	Fragile X syndrome	TP-PCR	SP-MG-10, ed. 5, 18.1.2019; MP-MG-03, ed.10, 31.1.2022; MP-MG-07, ed. 11, 23.1.2025; ABI PRISM 3130	Blood	A, B, D
11.	Examination of germline genome variants	MLPA	SP-MG-11, ed. 5, 18.1.2019; MP-MG-03, ed.10, 31.1.2022; MP-MG-07, ed. 11, 23.1.2025; MP-MG-13, ed. 3, 17.1.2019; ABI PRISM 3130	Blood	A, B, C, D

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12.	Examination of germline genome variants	aCGH	SP-MG-12, ed. 7, 25.1.2023, change 1, 2.5.2025; MP-MG-03, ed.10, 31.1.2022; MP-MG-14, ed. 4, 11.2.2019; MP-MG-15, ed. 2, 19.2.2018; Agilent SureScan Dx Microarray Scanner G5761AA	Blood, tissue, amniotic fluid, buccal smear	A, B, C, D
13.	Non-invasive prenatal testing (NIPT)	NGS	SP-MG-13, ed. 7, 3.7.2024; change 1, 23.9.2024; MP-MG-03, ed.10, 31.1.2022; MP-MG-07, ed. 11, 23.1.2025; MP-MG-11, ed. 11, 23.1.2025; MP-MG-12, ed. 10, 3.7.2024; MiSeq, NextSeq 500/550	Blood	A, B, C, D
14.	Examination of HLA system	SSP-PCR	SP-MG-14, ed. 2, 18.1.2019; MP-MG-03, ed.10, 31.1.2022;	Blood	A, B, C, D

Specification of the scope of accreditation:

Field Nr. / Ordinal Number	Detailed information on activities within the scope of accreditation
816/3	<i>FV</i> –Leiden (G1691A), <i>FII</i> -prothrombin (G22010A), <i>MTHFR</i> (C677T, A1298C).
816/4	Microdeletion on the Y chromosome

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Field Nr. / Ordinal Number	Detailed information on activities within the scope of accreditation
816/5	<i>CFTR</i>: diagnostic kit INNO-LiPA <i>CFTR</i>19, INNO-LiPA <i>CFTR</i>17+Tn Update: F508del, G542X, N1303K, W1282X, G551D, 1717-1G→A, R553X, <i>CFTR</i>dele2,3(21kb), I507del, 711+1G→T, 3272-26A→G, 3905insT, R560T, 1898+1G→A, S1251N, I148T, 3199del6, 3120+1G→A a Q552X, 621+1G→T, 3849+10kbC→T, 2183AA→G, 394delTT, 2789+5G→A, R1162X, 3659delC, R117H, R334W, R347P, G85E, 1078delT, A455E, 2143delT, E60X, 2184delA a 711+5G→A, IVS8 5T/7T/9T; <i>CFTR</i>: diagnostic kit StripAssayTMViennaLab: <i>CFTR</i>del2,3(21kb), I507del (-ATC), F508del (-CTT), 1717-1G>A, G542X, G551D, R553X, R560T, 2143delT, 2183AA>G, 2184delA, 2184insA, 2789+5G>A, R1162X, 3659delC, 3905insT, W1282X, N1303K; G85E, 394delTT, R117H, Y122X, 621+1G>T, 711+1G>T, 1078delT, R334W, R347H, R347P, A455E, 1898+1G>A, 3120+1G>A, 3272-26A>G, Y1092X, 3849+10kbC>T, IVS8 5T/7T/9T.
816/6	STR markers: <i>D13S 634</i>, <i>D13S 742</i>, <i>D13S 305</i>, <i>D13S 628</i>, <i>D18S 535</i>, <i>D18S 391</i>, <i>D18S 386</i>, <i>D18S 978</i>, <i>D18S 499</i>, <i>D21S 1435</i>, <i>D21S 11</i>, <i>D21S 1270</i>, <i>D21S 1411</i>, <i>P39</i>, <i>DXS 981</i>, <i>DXS 1187</i>, <i>XHPRT</i>, <i>DXS 996</i>, <i>DXS 1283E</i>, <i>DYS 448</i>, <i>SRY</i>, <i>X22</i>, <i>AMELX</i>, <i>AMELY</i>; Kit Devyser Complete v2: <i>D13S742</i>, <i>D13S634</i>, <i>D13S628</i>, <i>D13S305</i>, <i>D13S1492</i>, <i>D13S800</i>, <i>D13S252</i>, <i>D18S978</i>, <i>D18S535</i>, <i>D18S386</i>, <i>GATA178F11</i>, <i>D18S1364</i>, <i>D18S386</i>, <i>D18S1002</i>, <i>D18S976</i>, <i>D21S1435</i>, <i>D21S11</i>, <i>D21S1411</i>, <i>D21S1444</i>, <i>D21S1446</i>, <i>D21S1442</i>, <i>D21S2055</i>, <i>DXS1187</i>, <i>DXS981</i>, <i>XHPRT</i>, <i>DXS2390</i>, <i>SRY</i>, <i>T1</i>, <i>T3</i>, <i>DXYS267</i>, <i>DXYS218</i>, <i>ZFY</i>, <i>ZFX</i>, <i>AMELX</i>, <i>AMELY</i>.
816/7	<i>FV</i> –Leiden (G1691A), <i>FII</i> -prothrombin (G22010A), <i>MTHFR</i> (C677T, A1298C).
816/8	<i>BRCA1</i> , <i>BRCA2</i> .
816/9	ONKO solution: <i>ABRAXAS1</i>, <i>APC</i>, <i>ATM</i>, <i>BAP1</i>, <i>BARD1</i>, <i>BLM</i>, <i>BMPR1A</i>, <i>BRCA1</i>, <i>BRCA2</i>, <i>BRIP1</i>, <i>CDH1</i>, <i>CDK4</i>, <i>CDKN2A</i>, <i>CDKN2B</i>, <i>CHEK2</i>, <i>EPCAM</i>, <i>ERCC2</i>, <i>ERCC3</i>, <i>FANCC</i>, <i>FANCM</i>, <i>FH</i>, <i>FLCN</i>, <i>HOXB13</i>, <i>KIT</i>, <i>MEN1</i>, <i>MET</i>, <i>MLH1</i>, <i>MLH3</i>, <i>MRE11</i> (<i>MRE11A</i>), <i>MSH2</i>, <i>MSH6</i>, <i>MUTYH</i>, <i>NBN</i>, <i>NF1</i>, <i>NF2</i>, <i>PALB2</i>, <i>PIK3CA</i>, <i>PMS2</i>, <i>PMS2CL</i>, <i>POLD1</i>, <i>POLE</i>, <i>PRKARIA</i>, <i>PRSS1</i>, <i>PTEN</i>, <i>PTCH1</i>, <i>RAD50</i>, <i>RAD51C</i>, <i>RAD51D</i>, <i>RB1</i>, <i>RECQL</i>, <i>RECQL4</i>, <i>RET</i>, <i>SDHB</i>, <i>SLX4</i>, <i>SMAD4</i>, <i>SMARCB1</i>, <i>SPINK1</i>, <i>STK11</i>, <i>SUFU</i>, <i>TP53</i>, <i>TSC1</i>, <i>TSC2</i>, <i>VHL</i>, <i>WRN</i>, <i>WT1</i>, <i>XRCC2</i>. CLG Carrier Screen: <i>ACADM</i>, <i>ACADS</i>, <i>ACADVL</i>, <i>ADGRV1</i>(<i>GPR98</i>), <i>AGL</i>, <i>ALDOB</i>, <i>ALPL</i>, <i>AR</i>, <i>ARG1</i>, <i>ARSA</i>, <i>ASL</i>, <i>ASPA</i>, <i>ASS1</i>, <i>ATM</i>, <i>ATP7B</i>, <i>BCKDHA</i>, <i>BCKDHB</i>, <i>CBS</i>, <i>CDH23</i>, <i>CFTR</i>, <i>CLN3</i>, <i>CNGB3</i>, <i>COL4A5</i>, <i>CPT1A</i>, <i>CPT2</i>, <i>CTNS</i>, <i>CYP17A1</i>, <i>DBT</i>, <i>DHCR7</i>, <i>F2</i>, <i>F5</i>, <i>FAH</i>, <i>FSHR</i>, <i>G6PC1</i>, <i>GAA</i>, <i>GALT</i>, <i>GBA</i>, <i>GCDH</i>, <i>GJB2</i>, <i>GLA</i>, <i>GLB1</i>, <i>GLDC</i>, <i>GNPTAB</i>, <i>HADHA</i>, <i>HBB</i>, <i>HEXA</i>, <i>CHRNE</i>, <i>IDUA</i>, <i>IL2RG</i>, <i>IVD</i>, <i>MCCC1</i>, <i>MCCC2</i>, <i>MEFV</i>, <i>MTM1</i>, <i>MYO7A</i>, <i>NBN</i>, <i>NPC1</i>, <i>NPC2</i>, <i>OPA1</i>, <i>OTC</i>, <i>PAH</i>, <i>PCDH15</i>, <i>PEX1</i>, <i>PEX10</i>, <i>PEX12</i>, <i>PEX13</i>, <i>PEX14</i>, <i>PEX16</i>, <i>PEX2</i>, <i>PEX7</i>, <i>PKD1</i>, <i>PKD2</i>, <i>PKHD1</i>, <i>PMM2</i>, <i>POR</i>, <i>RAPSN</i>, <i>SERPINA1</i>(c.1096G>A), <i>SGSH</i>, <i>SLC22A5</i>, <i>SLC25A20</i>, <i>SLC26A4</i>, <i>SMN1</i>, <i>SMN2</i>, <i>SMPD1</i>, <i>TGMI</i>, <i>TPP1</i>, <i>USH1C</i>, <i>USH2A</i>.
816/11	<i>BRCA1</i> , <i>BRCA2</i> , <i>SMN1</i> , <i>SMN2</i> .
816/13	Chromosomes 13, 18, 21, X, Y; microdeletion syndromes: 1p36 deletion syndrome, Wolf-Hirschhorn syndrome (4p16.3), Cri-du-chat syndrome (5p15), Prader-Willi/Angelman syndrome (15q11), DiGeorge syndrome (22q11).
816/14	Alleles associated with celiac disease: HLA DQA1*02:01, *03:01, *05; HLA DQB1*02, *03:02

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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.

aCGH	array Comparative Genome Hybridization
FISH	Fluorescent In Situ Hybridization
MLPA	Multiplex Ligation-dependent Probe Amplification
NGS	Massive Parallel Sequencing
PCR	Polymerase Chain Reaction
Real-Time PCR	Quantitative Polymerase Chain Reaction
RFLP	Restriction Fragment Length Polymorphism
SSP-PCR	Polymerase Chain Reaction with Sequence Specific Primers
TP-PCR	Triplet Primed Repeat PCR