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: 23/01/2025

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. 11, 1.2.2024 MP-CG-03, ed. 1, 9.2.2019; MP-CG-02, ed. 1, 9.2.2019; N-CG-05, ed. 1, 9.2.2019; N-CG-06, ed. 1, 9.2.2019; N-CG-07, ed. 1, 9.2.2019; N-CG-08, ed. 1, 9.2.2019;	Amniotic fluid, blood, tissue	A, B, D
2.	Examination of constitutional chromosomal aberrations	FISH	SP-CG-02, ed. 6, 25.1.2023; change 1, 1.2.2024; N-CG-04, ed. 3, 9.2.2019; N-CG-05, ed. 1, 9.2.2019; N-CG-10, ed. 1, 9.2.2019; 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
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

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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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Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of method procedure/ equipment	Examined material	Degrees of freedom[1]
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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Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of method procedure/ equipment	Examined material	Degrees of freedom[1]
12.	Examination of germline genome variants	aCGH	SP-MG-12, ed. 7, 25.1.2023; 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	*FV* –Leiden (G1691A), *FII*-prothrombin (G22010A), *MTHFR* (C677T, A1298C).
816/4	Microdeletion on the Y chromosome

List of activities within the flexible scope of accreditation

Field Nr. / Ordinal Number	Detailed information on activities within the scope of accreditation
816/5	*CFTR*: diagnostic kit INNO-LiPA CFTR19, INNO-LiPA CFTR17+Tn Update: F508del, G542X, N1303K, W1282X, G551D, 1717-1G→A, R553X, CFTRdele2,3(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; *CFTR*: diagnostic kit StripAssay™ViennaLab: CFTRdel2,3(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: *D13S 634, D13S 742, D13S 305, D13S 628, D18S 535, D18S 391, D18S 386, D18S 978, D18S 499, D21S 1435, D21S 11, D21S 1270, D21S 1411, P39, DXS 981, DXS 1187, XHPRT, DXS 996, DXS 1283E, DYS 448, SRY, X22, AMELX, AMELY*; Kit Devyser Complete v2: *D13S742, D13S634, D13S628, D13S305, D13S1492, D13S800, D13S252, D18S978, D18S535, D18S386, GATA178F11, D18S1364, D18S386, D18S1002, D18S976, D21S1435, D21S11, D21S1411, D21S1444, D21S1446, D21S1442, D21S2055, DXS1187, DXS981, XHPRT, DXS2390, SRY, T1, T3, DXYS267, DXYS218, ZFY, ZFX, AMELX, AMELY.*
816/7	*FV* –Leiden (G1691A), *FII*-prothrombin (G22010A), *MTHFR* (C677T, A1298C).
816/8	*BRCA1, BRCA2.*
816/9	ONKO solution: *ABRAXAS1, APC, ATM, BAP1, BARD1, BLM, BMPR1A, BRCA1, BRCA2, BRIP1, CDH1, CDK4, CDKN2A, CDKN2B, CHEK2, EPCAM, ERCC2, ERCC3, FANCC, FANCM, FH, FLCN, HOXB13, KIT, MEN1, MET, MLH1, MLH3, MRE11 (MRE11A), MSH2, MSH6, MUTYH, NBN, NF1, NF2, PALB2, PIK3CA, PMS2, PMS2CL, POLD1, POLE, PRKAR1A, PRSS1, PTEN, PTCH1, RAD50, RAD51C, RAD51D, RB1, RECQL, RECQL4, RET, SDHB, SLX4, SMAD4, SMARCB1, SPINK1, STK11, SUFU, TP53, TSC1, TSC2, VHL, WRN, WT1, XRCC2.* CLG Carrier Screen: *ACADM, ACADS, ACADVL, ADGRV1(GPR98), AGL, ALDOB, ALPL, AR, ARG1, ARSA, ASL, ASPA, ASS1, ATM, ATP7B, BCKDHA, BCKDHB, CBS, CDH23, CFTR, CLN3, CNGB3, COL4A5, CPT1A, CPT2, CTNS, CYP17A1, DBT, DHCR7, F2, F5, FAH, FSHR, G6PC1, GAA, GALT, GBA, GCDH, GJB2, GLA, GLB1, GLDC, GNPTAB, HADHA, HBB, HEXA, CHRNE, IDUA, IL2RG, IVD, MCCC1, MCCC2, MEFV, MTM1, MYO7A, NBN, NPC1, NPC2, OPA1, OTC, PAH, PCDH15, PEX1, PEX10, PEX12, PEX13, PEX14, PEX16, PEX2, PEX7, PKD1, PKD2, PKHD1, PMM2, POR, RAPSN, SERPINA1(c.1096G>A), SGSH, SLC22A5, SLC25A20, SLC26A4, SMN1, SMN2, SMPD1, TGM1, TPP1, USH1C, USH2A.*
816/11	*BRCA1, BRCA2, SMN1, SMN2.*
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