EA MLA Signatory
Český institut pro akreditaci, o.p.s.
Olšanská 54/3, 130 00 Praha 3

issues

according to section 16 of Act No. 22/1997 Coll., on technical requirements for products, as amended

CERTIFICATE OF ACCREDITATION

No. **509/2023**

Fakultní nemocnice Hradec Králové
with registered office Sokolská 581, 500 05 Hradec Králové - Nový Hradec Králové,
Company Registration No. 00179906

for the Medical Laboratory No. **8234**
Molecular genetics laboratory of DCBD and DMG

Scope of accreditation:

Molecular genetic examinations of the human genome to the extent as specified in the appendix to this Certificate.

This Certificate of Accreditation is a proof of Accreditation issued on the basis of assessment of fulfillment of the accreditation criteria in accordance with

ČSN EN ISO 15189:2013

In its activities performed within the scope and for the period of validity of this Certificate, the Conformity Assessment Body is entitled to refer to this Certificate, provided that the accreditation is not suspended and the Accredited Body meets the specified accreditation requirements in accordance with the relevant regulations applicable to the activity of an accredited Conformity Assessment Body.

This Certificate of Accreditation replaces, to the full extent, Certificate No.: 227/2022 of 12. 5. 2022, or any administrative acts building upon it.

The Certificate of Accreditation is valid until: **6. 1. 2026**

Prague: 25. 9. 2023

Český institut pro akreditaci, o.p.s.
NÁRODNÍ AKREDITAČNÍ ORGÁN
– 1 –

Milena Lochmanová
Director of the Department
of Medical Laboratories
Czech Accreditation Institute

List of activities within the flexible scope of accreditation

Accredited Body: Fakultní nemocnice Hradec Králové

CAB Name: Molecular genetics laboratory of DCBD and DMG

CAB Number: 8234

Certificate of Accreditation No.: 509/2023

Field of Accreditation: Medical laboratory - ČSN EN ISO 15189:2013

Updated: 25. 9. 2023

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 unbalanced chromosomal aberrations	Array CGH	SOP 4-36-0038A, version 3, 17. 7. 2023, Annexes 1.1-1.9, 2; GeneChip Scanner 3000Dx; Affymetrix CytoScan 750K Array	Incoagulable blood - peripheral, cultured amniocytes, CVS cells, tissue, bone marrow, native amniotic fluid	A, B, C, D
2.	HLA system examination	PCR with electrophoretic product detection	SOP 4-36-0060 F, version 2, 26. 5. 2023, Annexs 3.1-3.4	Incoagulable blood - peripheral, cultured amniocytes, CVS cells, tissue, bone marrow	A, B, C, D
3.	Examination of germline genome variants	Methylation-specific MLPA	SOP 4-36-0061 F, version 2, 7. 8. 2023, Annexes 3-5; Genetic Analyzer ABI3500xL; ABI3500 Dx	Incoagulable blood - peripheral, cultured amniocytes, CVS cells, tissue, bone marrow	A, B, C, D
4.	Examination of germline genome variants	Real-Time PCR	SOP 4-36-0062 F, version 2, 26. 3. 2023, Annexes 3.1-3.3, 4.1-4.3, 5.1-5.3, 6.1-6.3, 7.1-7.3, 8.1-8.3, 9.1-9.3; Rotor-Gene 6000 2Plex/5Plex, Qiagen	Incoagulable blood - peripheral, cultured amniocytes, CVS cells, buccal smear, tissue, bone marrow	A, B, C, D

List of activities within the flexible scope of accreditation

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	PCR with fragment analysis	SOP 4-36-0063 F, version 2, 20. 6. 2023, Annexes 3.1-3.6, 4.1-4.4, 5.1-5.4, 6.1-6.4, 7.1-7.4; Genetic Analyzer ABI3500xL; ABI3500 Dx	Incoagulable blood - peripheral, cultured amniocytes, CVS cells, tissue, bone marrow, amniotic fluid	A, B, C, D
6.	Examination of germline genome variants	MLPA	SOP 4-36-0064 F, version 2, 7. 8. 2023, Annexes 4, 5; Genetic Analyzer ABI3500xL; ABI3500 Dx	Incoagulable blood - peripheral, cultured amniocytes, CVS cells, tissue, bone marrow	A, B, C, D
7.	Examination of germline genome variants	Direct sequencing (Sanger)	SOP 4-36-0065 F, version 2, 11. 8. 2023, Annexes 3.1-3.3, 4-6; Genetic Analyzer ABI3500xL; ABI3500 Dx	Incoagulable blood - peripheral, cultured amniocytes, CVS cells, buccal smear, tissue, bone marrow	A, B, C, D
8.	Examination of germline genome variants	NGS-MPS	SOP 4-36-0066 F, version 2, 11. 7. 2023; SOP 4-36-0056 A, version 2, 11. 7. 2023, Annexes 3-7; SOP 4-36-0078 A, version 2, 11. 7. 2023; MiSeq system, Illumina	Incoagulable blood - peripheral, buccal smear, tissue, bone marrow, FFPE	A, B, C, D
9.	Examination of somatic genome variants	NGS-MPS	SOP 4-36-0066 F, version 2, 11. 7. 2023; SOP 4-36-0057 A, version 2, 11. 7. 2023; SOP 4-36-0080 A, version 2, 11. 7. 2023; MiSeq system, Illumina	Incoagulable blood - peripheral, buccal smear, tissue, bone marrow, FFPE	A, B, C, D

List of activities within the flexible scope of accreditation

Specification of the scope of accreditation:

Field Nr. / Ordinal Number	Detailed information on activities within the scope of accreditation
816/1	CNV type
816/2	HLA-DQA1*05-DQB*02, HLA-DQA1*03-DQB1*0302
816/3	Locus:15q11
816/4	*F5* (c.1601G>A), *F2* (c.*97G>A), *HFE* (c.845G>A, c.187C>G, c.193A>T), MTHFR (c.665C>T) *TPMT* (c.238G>C, c.460G>A, c.719A>G), *CYP2C9* (c.430C:T, c.1075A>C), *VKOR1* (c.-1639G>A); *DPYD* (c.1236G>A, c.1679T>G, c.1905+1G>A, c.2846A>T)
816/5	**Examination of mutations in *CFTR* gene:** *711+1G>T, 2043delG, 1677delTA, W1282X, R1283M, K710X, 3849+10kbC>T, 2789+5G>A, M1101K, G85E, 3905insT, 1525-1G>A, 2184delA, 3659delC, N1303K, 2184insA, 1812-1G->A, CFTRdele2,3, 2143delT, Y569D, R1162X, A561E, S1251N, P67L, R1158X, 1609delCA, Q493X, E60X, 1898+1G>A, 1898+5G>T, I507del, F508del, V520F, 394delTT, D1152H, V232D, L218X, 621+2T>C, 1717-1G>A, L206W, E92X, 3120+1G>A, G542X, S549N, G551D, 712-1G>T, R553X, 3272-26A>G, R560T, 2183AA>G, R117H, R117C, 1811+1.6kbA>G, 2869insG, Y122X, Q890X, R1066C, R347H, R347P, 1161delC, 1154ins TC, E92K, I336K, R334W, Y1092X (C>A), 621+1G>T, 1078delT, A455E and IVS9 variants: 5T (including the identification of TG9-13)/7T/9T;* **Examination of post transplant chimerism using STR loci and amelogenin gene;** List of genetic loci used: CSF1PO, D2S1338, D18S51, D5S818, D7S820, D3S1358, D19S433, FGA, D8S1179, D13S317, TPOX, D21S11, D16S539, vWA, TH01, Amelogenin; **Aneuploidy of chromosomes 13,18,21 X and Y (STaR Optima1)**: DXS6854 (Xq26.1), AMEL (Xp22.31-Xp22.1 a Yp11.2), D18S391 (18p11.31), D13S352 (13q14.11), D21S1435 (21q21.1), D18S976 (18p11.31), SRY (Yp11.31), TAF9B (3p24.2 a Xq13.2-q13.3), D21S11 (21q21.1), D21S1444 (21q22.13), D13S742 (13q12.13), D21S1442 (21q21.3), D21S1246 (21q22.2), XHPRT (Xq26.1), D21S1409 (21q21.2), DXYS218 (Xp22.32 a Yp11.3), D18S386 (18q22.1), D13S634 (13q21.33), D18S819 (18q11.2), D13S628 (13q31.1), D13S305 (13q13.3), D18S535 (18q12.3); **Aneuploidy of chromosomes 15, 16, 22 (Optima PLUS)**: D15S195 (15q21), D15S652 (15q26), D15S659 (15q15), D15S822 (15q12), D15S657 (15q26), D16S539 (16q24.1), D16S2624 (16q22), D16S2616 (16p13.2), D16S2621 (16q23), D16S753 (16p11), D22S532 (22q13.31), D22S686 (22q11.2), D22S683 (22q12), D22S1045 (22q13.1), D22S691 (22q12)
816/6	*NF1, NF2, APC, ATM, BAP1, BARD1, BLM, BMPR1A, BRCA1, BRCA2, BRIP1, CDH1, CDK4, CDKN2A, CHEK2, FH, GREM, EPCAM, MLH1, MSH2, MSH6, MUTYH, NBN, PALB2, PMS2, POLD1, POLE, PTCH1, PTEN, RAD50, RAD51C, RAD51D, SMAD4, STK11, SUFU, TP53, SHOX, RUNX2, CYBA, CYBB, NCF2, NCF4, FOXF1, FGD1, SMN1, SMN2,* microdeletion syndromes 1, syndromes - *CMT1A1*
816/7	*NF1, NF2, APC, ATM, BAP1, BARD1, BLM, BMPR1A, BRCA1, BRCA2, BRIP1, CDH1, CDK4, CDKN2A, CHEK2, FH, GREM, EPCAM, MLH1, MSH2, MSH6, MUTYH, NBN, PALB2, PMS2, POLD1, POLE, PTCH1, PTEN, RAD50, RAD51C, RAD51D, SMAD4, STK11, SUFU, TP53, PMP22, DHCR7, GJB2, PHOX2B, RUNX2, SHOX, SOX2, KAT6B, FGFR3, HCCS, SPRED1 and TTN*
816/8	**NGS (Hereditary cancer syndromes):** *ABRAXAS1, AIP, ALK, APC, APEX1, ATM, ATMIN, ATR, ATRIP, AURKA, AXIN1, BABAM1, BAP1, BARD1, BLM, BMPR1A, BRAP, BRCA1, BRCA2, BRCC3, BABAM2 (BRE), BRIP1, BUB1B, EMSY (C11orf30), FAAP24 (C19orf40), casp8, CCND1, CDC73, CDH1, CDK4, CDKN1B, CDKN1C, CDKN2A, CEBPA, CLSPN, CSMD3, CSNK1E, CYLD,*

List of activities within the flexible scope of accreditation

	DCLRE1C, DDB2, DHFR, DICER1, DIS3, DIS3L2, DMBT1, DNAJC21, DPYD, EGFR, EGR1, EPCAM, EPHX1, EPOR, ERCC1, ERCC2, ERCC3, ERCC4, ERCC5, ERCC6, ESR1, ESR2, EXO1, EXT1, EZH2, FAN1, FANCA, FANCB, FANCC, FANCD2, FANCE, FANCF, FANCG, FANCI, FANCL, FANCM, FBXW7, FH, FLCN, GADD45A, GADD45G, GATA2, GPC3, GRB7, HELQ, HNF1A, HOXB13, HRAS, HUS1, HUS1B, CHEK1, CHEK2, KAT5, KCNJ5, KIT, LIG1, LIG3, LIG4, LMO1, LMO3, LRIG1, MAX, MCPH1, MDC1, MDM2, MDM4, MEN1, MET, MGMT, MLH1, MLH3, MMP8, MPL, MRE11 (MRE11A), MSH2, MSH3, MSH5, MSH6, MST1R, MTCP1, MUTYH, NAT1, NBN, NCAM1, NF1, NF2, NHEJ1, NSD1, NTHL1, OGG1, PALB2, PARP1, PARP2, PAXIP1, PCNA, PHB, PHB2, PHOX2B, PIK3CA, PIK3CG, PLA2G2A, PMS1, PMS2, POLB, POLD1, POLE, PPM1D, PREX1, PREX2, PRF1, PRKAR1A, PRKDC, PTEN, PTCH1, PTCH2, PTTG1, RAD1, RAD17, RAD18, RAD23A, RAD23B, RAD50, RAD51, RAD51AP1, RAD51B, RAD51C, RAD51D, RAD52, RAD54B, RAD54L, RAD9A, RB1, RBBP8, RBL1, RECQL, RECQL4, RECQL5, RET, REV3L, RFC1, RFC2, RFC4, RHBDF1, RHBDF2, RNF168, RNF169, RNF8, ROS1, RPA1, RUNX1, SBDS, SCARA5, SDHAF2, SDHB, SDHC, SDHD, SETX, SHPRH, SLX4, SMAD4, SMARCA4, SMARCB1, SMARCE1, SPINK1, SPRED1, SPRED2, SSC5D, STK11, SUFU, TCL1A, TELO2, TERF2, TERT, TLR2, TMEM127, TOPBP1, TOX2, TP53, TP53BP1, TP73, TRRAP, TSC1, TSC2, UBE2A, UBE2I, UBE2V2, UBE4B, UIMC1, VHL, VHLL, WRN, WT1, XPA, XPC, XRCC1, XRCC2, XRCC3, XRCC5, XRCC6, ZNF350; **NGS (Rasopathy):** *A2ML1, BRAF, CBL, HRAS, KRAS, LZTR1, MAP2K1 (MEK1), MAP2K2, MLH1, MSH6, NF1, NF2, NRAS, PMS2, PPP1CB, PTPN11, RAF1, RASA2, RIT1, RRAS, RRAS2, SHOC2, SOS1, SOS2, SPRED1, SPRED2;* **NGS (Hereditary non-syndromic hearing loss and deafness):** *ACTG1, ADCY1, AIFM1, ATP2B2, BDP1, BSND, CABP2, CCDC50, CD164, CDC14A, CDH23, CEACAM16, CIB2, CLDN14, CLDN9, CLIC5, CLRN2, COCH, COL11A1, COL11A2, COL4A6, CRYM, DCDC2, DIAPH1, DMXL2, ELMOD3, EPS8, EPS8L2, ESPN, ESRP1, ESRRB, EYA4, GAB1, GAS2, GIPC3, GJB2, GJB3, GJB6, GPSM2, GRAP, GRHL2, GRXCR1, GRXCR2, GSDME/DFNA5, HGF, HOMER2, IFNLR1, ILDR1, KARS, KCNQ4, KITLG, LHFPL5, LMX1A, LOXHD1, LRTOMT/COMT2, MAP1B, MARVELD2, MCM2, MET, MIR96 (MIRN96), MPZL2, MSRB3, MYH14, MYH9, MYO15A, MYO3A, MYO6, MYO7A, NARS2, NLRP3, OSBPL2, OTOA, OTOF, OTOG, OTOGL, P2RX2, PCDH15, PDE1C, PDZD7, PJVK, PLS1, PNPT1, POU3F4, POU4F3, PPIP5K2, PRPS1, PTPRQ, RDX, REST, RIPOR2 (FAM65B), ROR1, S1PR2, SCD5, SERPINB6, SIX1, SLC12A2, SLC17A8, SLC22A4, SLC26A4, SLC26A5, DIABLO (SMAC), SMPX, SPNS2, STRC, SYNE4, TBC1D24, TECTA, TJP2, TMC1, TMEM132E, TMIE, TMPRSS3, TNC, TPRN, TRIOBP, TRRAP, TSPEAR, USH1C, WBP2, WFS1, WHRN;* **MPS-digitalMLPA:** *APC, ATM, BAP1, BARD1, BMPR1A, BRCA1, BRCA2, BRIP1, CDH1, CDK4, CDKN2A, CHEK2, EPCAM, GREM1, MLH1, MSH2, MSH6, MUTYH, NBN, PALB2, PMS2, PTEN, RAD51C, RAD51D, SCG5, SMAD4, STK11 a TP53*
816/9	Examination of minimal residual disease in IGVH rearrangements using MPS Examination of somatic genome variants by MPS - genes: *ABL1, ANKRD26, ASXL1, ATM, BCL2, BCOR, BIRC3, BRAF, BTK, CALR, CARD11, CBL, CEBPA, CSF3R, DDX41, DNMT3A, ETNK1, ETV6, EZH2, FBXW7, FLT3, GATA1, GATA2, IDH1, IDH2, IKZF3, IRF4, JAK2, KIT, KRAS, MAP2K1, MCL1, MED12, MPL, MYD88, NFKBIE, NOTCH1, NPM1, NRAS, PHF6, PLCG2, POT1, PTPN11, RPS15, RUNX1, SAMHD1, SETBP1, SF3B1, SRSF2, STAG2, TET2, TP53, TRAF2, TRAF3, U2AF1, WT1, XPO1, ZRSR2*

List of activities within the flexible scope of accreditation

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.

Array CGH	Array Comparative Genome Hybridization
MLPA	Multiplex Ligation-dependent Probe Amplification
MPS	Massively parallel sequencing - Next Generation Sequencing
PCR	Polymerase Chain Reaction
CNV	Copy Number Variantion
HLA	Human Leucocyte Antigen (major histocompatibility complex of humans)
CVS	Chorionic Villus Sampling
FFPE	Formalin Fixed Paraffin Embedded