List of activities within the flexible scope of accreditation

Accredited Body: Univerzita Palackého v Olomouci

CAB Name: Institute of Molecular and Translational Medicine Laboratory of Experimental Medicine, UP Faculty of Medicine and Dentistry and University Hospital Olomouc

CAB Number: 8243

Certificate of Accreditation No.: 34/2023

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

Updated: 27. 1. 2023

Examinations:

Ordinal number	Analyte/parameter/ diagnostics	Principle of examination	Identification of method procedure/ equipment	Examined material	Degrees of freedom[1]
802 - Medical Microbiology					
1.	Detection and genotyping of human papillomavirus (HPV)	PCR method	C_SOP_20 version 3; Rotor-gene Q	Cervical, vaginal, cervicovaginal swabs	A, B
2.	Detection and genotyping of human papillomavirus (HPV)	Real-Time PCR	C_SOP_24 version 2; C_SOP_24 P2 version 2; C_SOP_24 P3 version 2; CFX96 real-time PCR system	Cervical, vaginal, cervicovaginal swabs	A, B, C
3.	Detection of SARS-CoV-2 virus	Real-Time PCR	C_SOP_21 version 3; C_SOP_21 P7 version 3; C_SOP_21 P9 version 3; CFX96 Touch real-time PCR system	Oropharyngeal, nasopharyngeal swabs, biological material collected through gargling	A, B, C
816 - Medical Genetics Laboratory					
1.	Examination of chromosomal aberrations	FISH	C_SOP_01 version 12	Tumor tissue, cell lines	A, B, C
2.	Examination of somatic variants of individual genes	Real-Time PCR	C_SOP_10 version 10; LOP 01v2; 02v2; 06v2; 13v2; 14v2; 25v2; 29v1; 30v1; 33v1; 35v2; Cobas Z; LC480	Isolated DNA, tissue (fresh, frozen, paraffin-embedded), plasma, cytological preparation, exudate, lavage	A, B, C

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Ordinal number	Analyte/parameter/ diagnostics	Principle of examination	Identification of method procedure/ equipment	Examined material	Degrees of freedom[1]
3.	Examination of somatic variants of individual genes	MPS	C_SOP_10 version 10; LOP 01v2; 02v2; 06v2; 13v2; 14v2; 25v2; 29v1; 30v1; 32v1; 34v2; 35v2; MiSeq, NovaSeq – platform Illumina	Isolated DNA and RNA, tissue (fresh, frozen, paraffin block), plasma, cytological preparation, exudate, ascites, lavage	A, B, C
4.	Examination of somatic gene variants in diagnostic panels	MPS	C_SOP_23 version 2; LOP 01v2; 02v2; 06v2; 08v1; 10v2; 13v2; 14v2; 16v2; 17v1; 18v1; 19v2; 20v2; 22v1; 26v1; 27v1; 28v2; 29v1; 30v1; MiSeq nebo NovaSeq – platform Illumina	Isolated DNA and RNA, tissue (fresh, frozen, paraffin-embedded), plasma, cytological preparation, exudate, ascites, lavage	A, B, C
5.	Examination of germline gene variants in the exome	MPS	C_SOP_17 version 6; LOP 01v2; 02v2; 03v2; 04v2,; 05v2; 06v2; 07v2; 08v1; 10v2; 11v1; 12v2; 13v2; 14v2; 15v2; NovaSeq, platform Illumina	Isolated DNA, tissue (fresh, frozen), blood, buccal swab, saliva	A, B, C
6.	Examination of CNV type chromosomal aberrations	a-CGH	C_SOP_14 version 6; GeneChip™ Scanner 3000 7G	Isolated DNA, cell lines, tissue (fresh, frozen, paraffin block), blood, bone marrow, ascites, lavage, mucosal swabs	A, B
7.	Examination of CNV type chromosomal aberrations	a-CGH	C_SOP_16 version 2; GeneChip™ Scanner 3000 7G	Chorionic villi, amniotic fluid	A, B
8.	Detection of circulating tumour cells	Fluorescence microscopy	C_SOP_22 version 2; CytoTrack CT11	Blood	A, B, C

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Specification of the scope of accreditation:

Field Nr. / Ordinal Number	Detailed information on activities within the scope of accreditation
802/1	Specific genotyping of HPV types 16 a 18 and concurrent detection of high-risk HPV 31, 33, 35, 39, 45, 51, 52, 59, 66, 67, 68
802/2	Genotyping of high-risk HPV 16, 18, 31, 33, 35, 39, 45, 51, 52 ,56, 58, 59, 66, 67, 68, 69, 73, 82; Genotyping of low-risk HPV 6, 11, 40, 42, 43, 44, 54, 61,70;
802/3	Genes *ORFlab, N, E, RdRp;*
816/1	*HER2, ALK, ROS1, NTRK1, EWSR1, SS18, TOP2A,* 1p36.3, 1q25.2, 19q13.32, 19q13.42, *EGFR, PTEN,* 9p21.3, *MDM2, RB1, p53*;
816/2	Gene *EGFR;*
816/3	Genes *KRAS, NRAS, BRAF, EGFR, IDH1, IDH2, POLE*;
816/4	Genes examined at DNA level (large panel of genes): *ABCB9, ABL1, ABL2, ACE2, ACVR1B, AKT1, AKT2, AKT3, ALK, ALPK2, AMER1, APC, AR, ARAF, ARID1A, ARID1B, ARID2, ARID5B, ASXL1, ASXL2, ATM, ATR, ATRX, AURKA, AURKB, AXIN1, AXIN2, AXL, B2M, BAP1, BARD1, BCL2, BCL2L1, BCL6, BCOR, BCORL1, BLM, BRAF, BRCA1, BRCA2, BRD4, BRIP1, BTK, C10orf54, CALR, CANX, CARD11, CASP8, CBFB, CBL, CCND1, CCND2, CCND3, CCNE1, CD200, CD274, CD276, CD40, CD40LG, CD48, CD70, CD79A, CD79B, CD80, CD86, CDC27, CDC73, CDH1, CDK12, CDK4, CDK6, CDK8, CDKN1A, CDKN1B, CDKN2A, CDKN2B, CDKN2C, CEBPA, CIC, CNKSR1, COL5A1, CREBBP, CRKL, CRLF2, CSF1R, CTCF, CTNNA1, CTNNB1, CTSB, CTSL, CTSS, CUL3, CUL4B, CUX1, CYLD, DAXX, DDR2, DDX3X, DICER1, DIS3, DMD, DNER, DNMT3A, DOT1L, EED, EGFR, EP300, EPCAM, EPHA3, EPHA5, EPHA7, EPHB1, ERAP1, ERAP2, ERBB2, ERBB3, ERBB4, ERCC1, ERCC2, ERCC3, ERCC4, ERCC5, ERG, ERRFI1, ESR1, ETV6, EWSR1, EXO1, EZH2, FAM46C, FANCA, FANCC, FANCD2, FANCE, FANCF, FANCG, FAS, FAT1, FBXW7, FGF19, FGF3, FGF4, FGFBP1, FGFR1, FGFR2, FGFR3, FGFR4, FH, FIGF, FKBP9, FLCN, FLT1, FLT3, FLT4, FOXA1, FOXL2, FOXP1, FUBP1, GABRA6, GADD45A, GATA1, GATA2, GATA3, GATA4, GATA6, GLI1, GNA11, GNA13, GNAQ, GNAS, GRIN2A, GSK3B, H3F3A, HERC1, HGF, HIST1H3B, HLA-A, HLA-B, HLA-C, HLA-E, HLA-F, HLA-G, HMGB1, HMGN1, HNF1A, HRAS, HSP90AA1, CHD4, CHEK1, CHEK2, ICOSLG, IDE, IDH1, IDH2, IFI30, IGF1R, IGF2, IGF2R, IKBKE, IKZF1, IL7R, INPP4B, IRF4, IRF6, IRS2, ITGAV, ITGB3, JAK1, JAK2, JAK3, JUN, KAT6A, KDM5A, KDM5C, KDM6A, KDR, KEAP1, KEL, KIT, KMT2A, KMT2C, KMT2D, KRAS, LGALS9, LGMN, LIG1, LIG3, LMO1, LNPEP, LPAR2, LRP1B, LZTR1, MAP2K1, MAP2K2, MAP2K4, MAP3K1, MCL1, MCM2, MCM3, MCM4, MCM5, MCM6, MCM7, MDM2, MDM4, MED12, MEF2B, MEN1, MET, MICA, MICB, MITF, MLH1, MLH3, MORC4, MPL, MR1, MRE11A, MSH2, MSH3, MSH4, MSH5, MSH6, MTOR, MUC17, MUTYH, MYB, MYC, MYCL, MYCN, MYD88, MYOCD, NBN, NCOR1, NF1, NF2, NFE2L2, NFKBIA, NKX2-1, NOTCH1, NOTCH2, NOTCH3, NOTCH4, NPEPPS, NPM1, NRAS, NRD1, NSD1, NTRK1, NTRK2, NTRK3, PALB2, PARK2, PARP1, PAX5, PBRM1, PCNA, PDCD1LG2, PDGFRA, PDGFRB, PDIA3, PDK1, PHF6, PIK3C2B, PIK3CA, PIK3CB, PIK3CG, PIK3R1, PIK3R2, PIM1, PLCG2, PMS1, PMS2, POLB, POLD1, POLD2, POLD3, POLD4, POLE, POLE4, PPP2R1A, PRDM1, PRKAR1A, PRKCG, PRKCI, PRKCZ, PRKDC, PSMA1, PSMA2, PSMA3, PSMA4, PSMA5, PSMA6, PSMA7, PSMA8, PSMB1, PSMB10, PSMB11, PSMB2, PSMB3, PSMB4, PSMB5, PSMB6, PSMB7, PSMB8, PSMB9, PSMC1, PSMC2, PSMC3, PSMC4, PSMC5, PSMC6, PSMD1, PSMD10, PSMD11, PSMD12, PSMD13, PSMD14, PSMD2, PSMD3, PSMD4, PSMD5, PSMD6, PSMD7, PSMD8, PSMD9, PSME1, PSME2, PSME3, PSME4, PSMF1, PSMG1, PSMG2, PSMG3, PSMG4, PTEN, PTGS2, PTCH1, PTPN11, PTPRD, QKI, RAC1, RAD17, RAD18, RAD21,*

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	RAD50, RAD51, RAD51C, RAF1, RARA, RASA1, RB1, RBM10, REL, RET, RFC1, RFC2, RFC3, RFC4, RFC5, RHEB, RHOA, RICTOR, RIT1, RNASEH2A, RNF43, ROS1, RPA1, RPA2, RPA3, RPA4, RPTOR, RUNX1, RUNX1T1, SDHA, SDHB, SDHC, SDHD, SETD2, SF3B1, SIRT1, SMAD2, SMAD3, SMAD4, SMARCA4, SMARCB1, SMC1A, SMC3, SMO, SOCS1, SOS1, SOX10, SOX17, SOX2, SOX9, SPEN, SPOP, SRC, SSBP1, STAG2, STAT3, STK11, SUFU, SUZ12, SYK, TAP1, TAP2, TAPBP, TAPBPL, TBX3, TCF7L2, TCP11L2, TDG, TERC, TERT, TET2, TGFBR2, TNF, TNFAIP3, TNFRSF14, TNFRSF9, TNFSF14, TNFSF18, TNFSF4, TNFSF9, TNKS, TOP1, TP53, TP53BP1, TP73, TPP2, TREX1, TRRAP, TSC1, TSC2, TSHR, U2AF1, VEGFA, VHL, VTCN1, WEE1, WT1, XPO1, XRCC5, ZFHX3, ZNF217; Genes examined at DNA level (small panels of genes): *NSCLC (lungs)* *ALK, ARAF, ATM, BRAF, CDK12, CDKN2A, DDR2, EGFR, ERBB2, FGFR1, FGFR2, FGFR3, KEAP1, KRAS, MAP2K1, MET, MTOR, NF1, NRAS, NTRK1, NTRK2, NTRK3, PIK3CA, PTEN, RET, STK11, TP53;* *Breast (breast and prostate)* *AKT1, ARID1A, ARID1B, ATM, ATR, BRAF, BRCA1, BRCA2, CDK12, CDKN2A, ERBB2, ESR1, FAT1, FGFR1, FGFR2, FGFR3, CHEK1, KEAP1, KRAS, MTOR, NF1, NRAS, NTRK1, NTRK2, NTRK3, PALB2, PIK3CA, PIK3R1, PTEN, RB1, STK11, TP53;* *CRC (colorectum)* *AKT1, ATM, BRAF, CDK12, CDKN2A, ERBB2, FGFR1, FGFR2, FGFR3, KEAP1, KRAS, MTOR, NF1, NRAS, NTRK1, NTRK2, NTRK3, PIK3CA, PTEN, STK11, TP53;* *Unknown and other* *AKT1, ALK, ARAF, ARID1A, ARID1B, ATM, ATR, BRAF, BRCA1, BRCA2, CDK12, CDKN2A, DDR2, EGFR, ERBB2, ESR1, FAT1, FGFR1, FGFR2, FGFR3, CHEK1, IDH1, IDH2, KEAP1, KRAS, MAP2K1, MET, MTOR, NF1, NRAS, NTRK1, NTRK2, NTRK3, PALB2, PIK3CA, PIK3R1, PTEN, RB1, RET, STK11, TP53;* Genes examined at RNA level: *ABL1, ACSL3, ACTG1, ACVR2A, ADAM17, ADAM28, ADGRG7, ADORA2A, AFF3, AGK, AKAP9, AKNA, AKT1, AKT3, ALK, ANP32B, AOAH, APOE, APP, ARHGAP26, ARHGAP9, ARL17A, ASPSCR1, ATF1, ATIC, ATM, ATXN2L, AXL, B2M, BAG4, BAIAP2L1, BANK1, BATF, BCL11A, BCL2, BCL6, BCOR, BCR, BIRC3, BLK, BNIP3L, BRAF, BRD3, BRD4, BTLA, BTNL2, CACNA2D2, CAMTA1, CANT1, CAPZB, CARD11, CARD16, CARS, CBFB, CCDC6, CCL1, CCL13, CCL17, CCL22, CCL4, CCL5, CCL7, CCNB3, CCND1, CCND3, CCR2, CCR3, CCR6, CD109, CD160, CD19, CD1A, CD1B, CD1E, CD2, CD200, CD200R1, CD209, CD244, CD247, CD27, CD274, CD276, CD28, CD38, CD3D, CD3E, CD3G, CD40, CD40LG, CD44, CD48, CD52, CD6, CD68, CD69, CD70, CD74, CD79A, CD80, CD86, CD8A, CD8B, CDK2, CDK6, CDKN2A, CDX1, CEP85L, CEP89, CIC, CIITA, CITED2, CLCN6, CLEC11A, CLIP4, CLTC, CMA1, CMKLR1, COL1A1, COL6A3, CORO1A, CORO1B, CR2, CREB1, CREB3L1, CREB3L2, CREBBP, CREM, CRTC1, CSF1, CSF2, CSF3R, CSNK1E, CTLA4, CTNNB1, CTSG, CUX1, CX3CL1, CXCL10, CXCL11, CXCL13, CXCL5, CXCL9, CXCR4, CXCR6, CXorf67, DAZL, DCTN1, DDIT3, DDX5, DEK, DNAH5, DOCK9, DPP4, DUSP22, DVL2, EBI3, EGFR, EHD1, EIF4A1, ELK4, EML4, EOMES, EPC1, ERBB2, ERBB3, ERC1, ERG, ESR1, ESRP1, ETV1, ETV4, ETV5, ETV6, EWSR1, EZR, F13A1, FAM131B, FAS, FER, FEV, FEZ1, FGF1, FGFR1, FGFR2, FGFR3, FGR, FCHSD1, FIP1L1, FLI1, FLT3, FLT3LG, FMNL1, FN1, FOXJ1, FOXL2, FOXN3, FOXO1, FOXO4, FOXP3, FPR2, FUS, FUT5, FYB1, GATA3, GATM, GBA2,*

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	GBP1, GCC2, GLI1, GLRX5, GNA11, GNAI1, GNAQ, GOLGA5, GOPC, GTF3C1, GZMA, GZMB, GZMM, HACL1, HAVCR2, HERPUD1, HEY1, HHLA2, HIP1, HIVEP1, HIVEP2, HLA-A, HLA-B, HLA-C, HLA-DMA, HLA-DMB, HLA-DOA, HLA-DOB, HLA-DPA1, HLA-DPB1, HLA-DQA1, HLA-DQA2, HLA-DQB1, HLA-DQB2, HLA-DRA, HLA-DRB1, HLA-DRB5, HLA-E, HLA-F, HLA-G, HLA-H, HMGA2, HNRNPA2B1, HOOK3, HSD11B1, CHIC2, CHIT1, ICOS, ICOSLG, IDH1, IDH2, IDO1, IDO2, IFI16, IFI27, IFI30, IFI44L, IFITM1, IFNG, IGHA1, IGHM, IGLL5, IGSF6, IKZF1, IL12RB2, IL15RA, IL17A, IL17RA, IL21R, IL26, IL2RB, IL3RA, IL5RA, INHBA, INSR, IRF1, IRF2, IRF2BP2, ITGA4, ITGAV, ITGB2, ITGB3, ITGB7, ITK, ITPKA, JAK1, JAK2, JAZF1, KANSL1, KIAA1217, KIF5B, KIR3DL1, KIT, KLC1, KLF17, KLK2, KLRC1, KLRD1, KMT2A, KRAS, KTN1, LAG3, LAIR1, LAIR2, LAMP3, LARGE1, LEUTX, LGALS9, LGR5, LILRB1, LILRB3, LMNA, LRIG3, LSM14A, LSM4, LST1, LTA, LTA4H, LTK, LYN, MAF, MALT1, MAML2, MAML3, MAN2A1, MAP3K14, MAPK13, MARCO, MAST1, MAST2, MBTD1, MEAF6, MED12, MET, MICA, MICB, MKL1, MKL2, MKRN1, MLF1, MLLT10, MME, MPPED1, MPRIP, MR1, MS4A1, MS4A2, MSMB, MSN, MSR1, MUSK, MYB, MYC, MYO1F, MYO5A, NAB2, NAIP, NCOA1, NCOA2, NCOA4, NCR1, NDRG1, NEFL, NFAM1, NFATC2, NFATC4, NFKB2, NFKBIL1, NKG7, NOTCH1, NOTCH2, NPM1, NR4A3, NRAS, NRG1, NRP1, NTRK1, NTRK2, NTRK3, NUMBL, NUP107, NUP214, NUTM1, NUTM2A, NUTM2B, OAS3, ODF2, OPTN, P2RY8, PAPSS1, PATZ1, PAX3, PAX5, PAX7, PAX8, PBX1, PBX3, PCM1, PDCD1, PDCD1LG2, PDGFB, PDGFRA, PDGFRB, PHF1, PHKG2, PIK3CA, PIM1, PKN1, PLA2G2D, PLA2G6, PLAG1, PMCH, POU2AF1, POU5F1, PPARG, PPFIBP1, PPIF, PRCC, PRDM10, PRDM16, PRF1, PRG2, PRKAR1A, PRKCA, PRKCB, PRRC2B, PSMB10, PSMB9, PTEN, PTGDR2, PTPRCAP, PTPRK, PWWP2A, RAD51, RAF1, RANBP2, RBL2, REL, RELA, REPS1, RET, RHOC, RNF130, RORC, ROS1, RRAD, RSPO2, RSPO3, RUNX1, RUNX1T1, S100A10, S100A7, SDC4, SEC31A, SELL, SERPINA3, SERPINB9, SET, SFPQ, SH3BP5, SHMT2, SIGMAR1, SLC34A2, SLC3A2, SLC45A3, SMAD2, SMAD3, SMARCA5, SMPD3, SND1, SP3, SQSTM1, SRF, SRGAP3, SS18, SS18L1, SSX1, SSX2, SSX4B, STARD3NL, STAT1, STAT4, STAT6, STIL, STRN, SUZ12, SYK, SYT17, SYTL1, TACC1, TACC3, TAF15, TAP1, TAP2, TAPBPL, TBL1XR1, TBX21, TCF12, TCF3, TCF7L2, TEAD1, TERT, TFE3, TFEB, TFG, TGFB1, THADA, THAP4, THBS1, TIA1, TIGIT, TIMP1, TMC8, TMIGD2, TMPRSS2, TNFRSF13B, TNFRSF14, TNFRSF17, TNFRSF18, TNFRSF19, TNFRSF25, TNFRSF4, TNFRSF8, TNFRSF9, TNFSF14, TNFSF15, TNFSF4, TNFSF9, TOM1L2, TOMM40, TP63, TPM3, TPM4, TPR, TPSAB1, TRA2B, TRAC, TRGC1, TRGC2, TRIM24, TRIM27, TRIM33, TXK, UBE2L3, USP6, USP9Y, VAV1, VCL, VGLL2, VSIR, VSNL1, VTCN1, VTI1A, WHSC1L1, WT1, YAP1, YWHAE, ZC3H7B, ZFYVE9, ZNF205, ZNF703, ZSCAN30;
816/5	Virtual panel of genes, defined HP: 0000118 f phenotypic abnormalities or its parts (4904 genes, see https://hpo.jax.org/app/browse/term/HP:0000118);
816/8	anti-CK (pancytokeratin), anti-EpCAM (epithelial cell adhesion molecule), anti-CD45 (leukocyte antigen).

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 analytes / parameters

D – Flexibility concerning the material to be examined

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

List of activities within the flexible scope of accreditation

PCR	Polymerase Chain Reaction
Real-Time PCR	Real-Time Polymerase Chain Reaction
FISH	Fluorescence In Situ Hybridization
MPS	Massively parallel sequencing (NGS)
a-CGH	Comparative genomic hybridization on oligonucleotide microarrays
CNV	Copy Number Variation