



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. 5. 2024

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 3; C_SOP_24 P2 version 3; C_SOP_24 P3 version 3; C_SOP_24 P4 version 3; C_SOP_24 P5 version 3; 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

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Ordinal number	Analyte/parameter/diagnostics	Principle of examination	Identification of method procedure/ equipment	Examined material	Degrees of freedom ¹
2.	Examination of somatic variants of individual genes	Real-Time PCR	C_SOP_10 verze 10; LOP 01v1.1; 02v2.1; 06v2.1; 13v2.1; 14v2.1; 29v1.1; 30v1.1; 33v1.1; 35v2.1; Cobas Z; LC480	Isolated DNA, tissue (fresh, frozen, paraffin-embedded), plasma, cytological preparation, exudate, lavage	A, B, C
3.	Examination of somatic variants of individual genes	MPS	C_SOP_10 verze 10; LOP 01v1.1; 02v2.1; 06v2.1; 13v2.1; 14v2.1; 29v1.1; 30v1.1; 32v1.1; 34v2; 35v2.1; MiSeq, NovaSeq – platforma 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 verze 3; LOP 01v1.1; 02v2.1; 06v2.1; 08v1.1; 10v2.1; 13v2.1; 14v2.1; 16v2.1; 17v1.1; 18v1.1; 19v2.1; 22v1.1; 27v1.1; 28v2.1; 29v1.1; 30v1.1; 41v1; MiSeq, NovaSeq nebo NextSeq2000 – platforma 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 verze 6; LOP 01v1.1; 02v2.1; 04v2.1; 05v2.1; 06v2.1; 07v2.1; 08v1.1; 10v2.1; 12v2.1; 13v2.1; 14v2.1; 15v2.1; NovaSeq, platforma 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

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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

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 <i>ORFlab, N, E, RdRp</i> ;
816/1	<i>HER2, ALK, ROS1, NTRK1, EWSR1, SS18, TOP2A, 1p36.3, 1q25.2, 19q13.32, 19q13.42, EGFR, PTEN, 9p21.3, MDM2, RB1, p53</i> ;
816/2	Gene <i>EGFR</i> ;
816/3	Genes <i>KRAS, NRAS, BRAF, EGFR, IDH1, IDH2, POLE</i> ;
816/4	Genes examined at DNA level (large panel of genes): <i>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, CBF, 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, CNKSRI, COL5A1, CREBBP, CRKL, CRLF2, CSF1R, CTCF, CTNNA1, 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, ERFF1, ESRI, ETV6, EWSR1, EXO1, EZH2, FAM46C, FANCA, FANCC, FANCD2, FANCE, FANCF, FANCG, FAS, FAT1, FBXW7, FGF19, FGF3, FGF4, FGF3P1, 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,</i>

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H3F3A, HERC1, HGF, HIST1H3B, HLA-A, HLA-B, HLA-C, HLA-E, HLA-F, HLA-G, HMGB1, HMGNI, 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, PRKARIA, 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, 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, ZFH3, 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, ESRI, 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, ESRI, 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;

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	<p>Genes examined at RNA level:</p> <p><i>ABL1, ACSL3, ACTG1, ACVR2A, ADAM17, ADAM28, ADGRG7, ADORA2A, AFF3, AGK, AKAP9, AKNA, AKT1, AKT3, ALK, ANP32B, AOA1, 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, CBF3, 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, CRTCL1, CSF1, CSF2, CSF3R, CSNK1E, CTLA4, CTNNA1, CTNNA2, CTNNA3, CTNNA4, CTNNA5, CTNNA6, CTNNA7, CTNNA8, CTNNA9, CTNNA10, CTNNA11, CTNNA12, CTNNA13, CTNNA14, CTNNA15, CTNNA16, CTNNA17, CTNNA18, CTNNA19, CTNNA20, CTNNA21, CTNNA22, CTNNA23, CTNNA24, CTNNA25, CTNNA26, CTNNA27, CTNNA28, CTNNA29, CTNNA30, CTNNA31, CTNNA32, CTNNA33, CTNNA34, CTNNA35, CTNNA36, CTNNA37, CTNNA38, CTNNA39, CTNNA40, CTNNA41, CTNNA42, CTNNA43, CTNNA44, CTNNA45, CTNNA46, CTNNA47, CTNNA48, CTNNA49, CTNNA50, CTNNA51, CTNNA52, CTNNA53, CTNNA54, CTNNA55, CTNNA56, CTNNA57, CTNNA58, CTNNA59, CTNNA60, CTNNA61, CTNNA62, CTNNA63, CTNNA64, CTNNA65, CTNNA66, CTNNA67, CTNNA68, CTNNA69, CTNNA70, CTNNA71, CTNNA72, CTNNA73, CTNNA74, CTNNA75, CTNNA76, CTNNA77, CTNNA78, CTNNA79, CTNNA80, CTNNA81, CTNNA82, CTNNA83, CTNNA84, CTNNA85, CTNNA86, CTNNA87, CTNNA88, CTNNA89, CTNNA90, CTNNA91, CTNNA92, CTNNA93, CTNNA94, CTNNA95, CTNNA96, CTNNA97, CTNNA98, CTNNA99, CTNNA100, CTNNA101, CTNNA102, CTNNA103, CTNNA104, CTNNA105, CTNNA106, CTNNA107, CTNNA108, CTNNA109, CTNNA110, CTNNA111, CTNNA112, CTNNA113, CTNNA114, CTNNA115, 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CTNNA516, CTNNA517, CTNNA518, CTNNA519, CTNNA520, CTNNA521, CTNNA522, CTNNA523, CTNNA524, CTNNA525, CTNNA526, CTNNA527, CTNNA528, CTNNA529, CTNNA530, CTNNA531, CTNNA532, CTNNA533, CTNNA534, CTNNA535, CTNNA536, CTNNA537, CTNNA538, CTNNA539, CTNNA540, CTNNA541, CTNNA542, CTNNA543, CTNNA544, CTNNA545, CTNNA546, CTNNA547, CTNNA548, CTNNA549, CTNNA550, CTNNA551, CTNNA552, CTNNA553, CTNNA554, CTNNA555, CTNNA556, CTNNA557, CTNNA558, CTNNA559, CTNNA560, CTNNA561, CTNNA562, CTNNA563, CTNNA564, CTNNA565, CTNNA566, CTNNA567, CTNNA568, CTNNA569, CTNNA570, CTNNA571, CTNNA572, CTNNA573, CTNNA574, CTNNA575, CTNNA576, CTNNA577, CTNNA578, CTNNA579, CTNNA580, CTNNA581, CTNNA582, CTNNA583, CTNNA584, CTNNA585, CTNNA586, CTNNA587, CTNNA588, CTNNA589, CTNNA590, CTNNA591, CTNNA592, CTNNA593, CTNNA594, CTNNA595, CTNNA596, CTNNA597, CTNNA598, CTNNA599, CTNNA600, CTNNA601, CTNNA602, CTNNA603, CTNNA604, CTNNA605, CTNNA606, CTNNA607, CTNNA608, CTNNA609, CTNNA610, CTNNA611, CTNNA612, CTNNA613, CTNNA614, CTNNA615, CTNNA616, CTNNA617, CTNNA618, CTNNA619, CTNNA620, CTNNA621, CTNNA622, CTNNA623, CTNNA624, CTNNA625, CTNNA626, CTNNA627, CTNNA628, CTNNA629, CTNNA630, CTNNA631, CTNNA632, CTNNA633, CTNNA634, CTNNA635, CTNNA636, CTNNA637, CTNNA638, CTNNA639, CTNNA640, CTNNA641, CTNNA642, CTNNA643, CTNNA644, CTNNA645, CTNNA646, CTNNA647, CTNNA648, CTNNA649, CTNNA650, CTNNA651, CTNNA652, CTNNA653, CTNNA654, CTNNA655, CTNNA656, CTNNA657, CTNNA658, CTNNA659, CTNNA660, CTNNA661, CTNNA662, CTNNA663, CTNNA664, CTNNA665, CTNNA666, CTNNA667, CTNNA668, CTNNA669, CTNNA670, CTNNA671, CTNNA672, CTNNA673, CTNNA674, CTNNA675, CTNNA676, CTNNA677, CTNNA678, CTNNA679, CTNNA680, CTNNA681, CTNNA682, CTNNA683, CTNNA684, CTNNA685, CTNNA686, CTNNA687, CTNNA688, CTNNA689, CTNNA690, CTNNA691, CTNNA692, CTNNA693, CTNNA694, CTNNA695, CTNNA696, CTNNA697, CTNNA698, CTNNA699, CTNNA700, CTNNA701, CTNNA702, CTNNA703, ZSCAN30;</i></p>
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List of activities within the flexible scope of accreditation

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.

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