

**The Appendix is an integral part of  
Certificate of Accreditation No. 696/2021 of 29/12/2021**

Accredited entity according to ČSN EN ISO 15189:2013:

**Univerzita Palackého v Olomouci**  
Institute of Molecular and Translational Medicine  
Laboratory of Experimental Medicine  
UP Faculty of Medicine and Dentistry and University Hospital Olomouc  
Hněvotínská 1333/5, 779 00 Olomouc

**Medical laboratory locations:**

1. **Laboratory of Molecular Carcinogenesis and Cytogenetics** Hněvotínská 1333/5, 779 00 Olomouc
2. **DNA Laboratory** Hněvotínská 1333/5, 779 00 Olomouc
3. **RNA Laboratory** Hněvotínská 1333/5, 779 00 Olomouc

*The Laboratory has a flexible scope of accreditation permitted as detailed in the Annex. Updated list of activities provided within the flexible scope of accreditation is available from the Laboratory on the website of the Institute of Molecular and Translational Medicine [www.umtm.cz](http://www.umtm.cz)*

**Examinations:**

Ordinal number	Examination procedure name	Examination procedure identification	Examined object
<b>816 - Medical Genetics Laboratory</b>			
1 <sup>(1)</sup>	Examination of cytogenetic changes by fluorescence <i>in situ</i> hybridization	C_SOP_01	Tumour tissue (print, paraffin section), cell lines (cytospin)
2	Reserved		
3 <sup>(2)</sup>	Examination of somatic variants of genes by real-time PCR	C_SOP_10, Annex No. 4, 8	Isolated genomic DNA, fresh or frozen tissue, paraffin block, plasma, cytologic preparation, exudate, lavage
4 <sup>(2)</sup>	Examination of somatic variants of genes by quick massive parallel sequencing	C_SOP_10, Annex No. 7	Isolated genomic DNA, fresh or frozen tissue, paraffin block, cytologic preparation, exudate, lavage
5 <sup>(3)</sup>	Detection of chromosomal aberrations on a whole genome level by microarrays method for the purpose of Copy Number Variation (CNV) analysis	C_SOP_14	Genomic DNA isolated from cell lines and biological materials – fresh or frozen tissue, paraffin block, blood, bone marrow, ascites, lavage, swabs of mucous membranes
6 <sup>(2)</sup>	Examination of somatic variants of genes by quick massive parallel sequencing	C_SOP_10, Annex No. 5, 6	Isolated genomic DNA, fresh or frozen tissue, paraffin block, blood

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Ordinal number	Examination procedure name	Examination procedure identification	Examined object
7 <sup>(3)</sup>	Prenatal detection of fetal chromosomal aberrations on a whole genome level by microarrays method for the purpose of Copy Number Variation (CNV) analysis	C_SOP_16	Genomic DNA isolated from fetal cells acquired by sampling chorionic villi or by amniocentesis
8 <sup>(2)</sup>	Clinical whole exome sequencing for the detection of germinal genetic variants of hereditary diseases by massive parallel sequencing method	C_SOP_17	Isolated genomic DNA, fresh or frozen tissue, blood, buccal swabs of mucous membranes, saliva
9. <sup>(3)</sup>	Detection of circulating tumour cells by fluorescence microscopy	C_SOP_22	Peripheral blood
10. <sup>(2)</sup>	Examination of somatic mutations and polymorphisms of a panel of 10 to 684 genes by massively parallel sequencing	C_SOP_23	Genomic DNA or RNA isolated from biological materials: fresh or frozen tissue, paraffin block, plasma, ascites, lavage, cervical swab, cervicovaginal swab
<b>802 - Medical microbiology</b>			
1 <sup>(1)</sup>	Reserved		
2 <sup>(1)</sup>	Reserved		
3 <sup>(1)</sup>	Genotyping of high- and low-risk HPV subtypes by hybridization method in a specialized Comprehensive oncology centre	C_SOP_19	Cervical, vaginal or cervicovaginal swabs or DNA from these swabs

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Ordinal number	Examination procedure name	Examination procedure identification	Examined object
4 <sup>(1)</sup>	Detection of hrHPV and genotyping of HPV16 and HPV18 using polymerase chain reaction in a specialized Comprehensive oncology centre	C_SOP_20	Cervical, vaginal or cervicovaginal swabs or DNA from these swabs
5. <sup>(1)</sup>	Detection of SARS-CoV-2 virus by real-time PCR	C_SOP_21, Annex 7, 9	Nasopharyngeal, oropharyngeal swabs, biological material obtained by gargling or RNA isolated from these materials
6. <sup>(1)</sup>	Genotyping of human papillomavirus by multiplex real-time PCR within a specialized Comprehensive Cancer Center	C_SOP_24, Annex 2, 3	Mucosal swabs or DNA from such swabs, total DNA isolated from fresh or frozen tissue

**Annex:**

Flexible scope of accreditation

Examination procedure ordinal numbers:
<i>Field of expertise 816: 3, 4, 6, 8, 10; field of expertise 802: 5, 6;</i>

The Laboratory is allowed to modify the examination procedures listed in the Annex within the specified scope of accreditation provided the measuring principle is observed.

The flexible approach to the scope of accreditation cannot be applied to the examinations not included in the Annex.

Explanations: Superscript at the examination procedure ordinal number identifies the workplace performing the examination.

SOP	Specification of examined genes
C_SOP_07	Carcinoembryonic antigen (CEA), epidermal growth factor receptor 1 (EGFR1), mammaglobin 1 (MGB1), glyceraldehyde 3-phosphate dehydrogenase (GAPDH), cytokeratin 19 (CK19), cytokeratin 20 (CK20), epithelial cell adhesion molecule (EpCAM), thyroid transcription factor (TTF1).
C_SOP_10, Annex No. 8	<i>EGFR</i> for lung carcinoma
C_SOP_10, Annex No. 4	<i>BRAF</i> for lung melanoma and carcinoma
C_SOP_10, Annex No. 7	<i>KRAS, NRAS, BRAF</i> for colorectal carcinoma and lung carcinoma; <i>NRAS, BRAF</i> for melanoma; <i>EGFR, BRAF</i> for lung carcinoma; <i>IDH1, IDH2</i> for glioma
C_SOP_10, Annex No. 5, 6	<i>BRCA1, BRCA2</i> for breast, ovarian, pancreatic and prostate tumours



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SOP	Specification of examined genes
	<p><i>PIK3C2G, PIK3C3, PIK3CA, PIK3CB, PIK3CD, PIK3CG, PIK3R1, PIK3R2, PIK3R3, PIMI, PLCG2, PLK2, PMAIP1, PMS1, PMS2, PNRC1, POLB, POLD1, POLD2, POLD3, POLD4, POLE, POLE4, PPARG, PPM1D, PPP2R1A, PPP2R2A, PPP6C, PRDM1, PREX2, PRKARIA, PRKCG, PRKCI, PRKCZ, PRKDC, PRSS8, 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, PTPRS, PTPRT, QKI, RAB35, RAC1, RAD17, RAD18, RAD21, RAD50, RAD51, RAD51B, RAD51C, RAD51D, RAD52, RAD54L, RAF1, RANBP2, RARA, RASA1, RB1, RBM10, RECQL4, REL, RET, RFC1, RFC2, RFC3, RFC4, RFC5, RFWD2, RHEB, RHOA, RICTOR, RITI, RNASEH2A, RNF43, ROS1, RPA1, RPA2, RPA3, RPA4, RPS6KA4, RPS6KB1, RPS6KB2, RPTOR, RUNX1, RUNX1T1, RYBP, SDHA, SDHAF2, SDHB, SDHC, SDHD, SETBP1, SETD2, SF3B1, SH2B3, SH2D1A, SHQ1, SIRT1, SLIT2, SLX4, SMAD2, SMAD3, SMAD4, SMARCA4, SMARCB1, SMARCD1, SMC1A, SMC3, SMO, SNCAIP, SOCS1, SOS1, SOX10, SOX17, SOX2, SOX9, SPEN, SPOP, SPTA1, SRC, SRSF2, SSBP1, STAG1, STAG2, STAT3, STAT4, STAT5A, STAT5B, STK11, STK40, SUFU, SUZ12, SYK, TAF1, TAP1, TAP2, TAPBP, TAPBPL, TBX3, TCEB1, TCF3, TCF7L2, TCP11L2, TDG, TERC, TERT, TET1, TET2, TFE3, TFRC, TGFBRI, TGFBR2, TMEM127, TMPRSS2, TNF, TNFAIP3, TNFRSF14, TNFRSF9, TNFSF14, TNFSF18, TNFSF4, TNFSF9, TNKS, TOP1, TOP2A, TP53, TP53BP1, TP63, TP73, TPP2, TRAF2, TRAF7, TREX1, TRRAP, TSC1, TSC2, TSHR, U2AF1, VEGFA, VEGFD, VHL, VTCN1, WEE1, WISP3, WT1, XIAP, XPO1, XRCC2, XRCC5, YAP1, YES1, ZBTB2, ZBTB7A, ZFH3, ZNF217, ZNF703, ZRSR2.</i></p> <p>Genes, examined at RNA level: <i>ABLI, AKT3, ALK, AR, AXL, BCL2, BRAF, BRCA1, BRCA2, CDK4, CSF1R, EGFR, EML4, ERBB2, ERG, ESRI, ETS1, ETV1, ETV4, ETV5, EWSR1, FGFR1, FGFR2, FGFR3, FGFR4, FLI1, FLT1, FLT3, JAK2, KDR, KIF5B, KIT, MET, MLL, MLLT3, MSH2, MYC, NOTCH1, NOTCH2, NOTCH3, NRG1, NTRK1, NTRK2, NTRK3, PAX3, PAX7, PDGFRA, PDGFRB, PIK3CA, PPARG, RAF1, RET, ROS1, RPS6KB1, TMPRSS2.</i></p> <p>It is acceptable that only a part of the listed genes (10 to 684) is examined using the method.</p>
C_SOP_24, Annex 2	The test allows full genotyping of 14 hrHPV ( <i>HPV16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68</i> ).
C_SOP_24, Annex 3	The test allows full genotyping of 19 hrHPV ( <i>HPV16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 56, 58, 59, 66, 68, 69, 73 and 82</i> ) and 9 lrHPV ( <i>HPV6, 11, 40, 42, 43, 44, 54, 61 and 70</i> ).