The Appendix is an integral part of
Certificate of Accreditation No. 155/2022 of 25/03/2022

Accredited entity according to ČSN EN ISO 15189:2013:

Fakultní nemocnice Brno
Laboratories of the Department of Pathology
Jihlavská 340/20, 625 00 Brno

Medical laboratory locations:

1. **Workplace NBP-Bohunice** Jihlavská 340/20, 625 00 Brno
2. **Workplace NBP-Maternity Hospital** Obilní trh 526/11, 602 00 Brno
3. **Workplace DN** Černopolní 212/9, 613 00 Brno

1. Workplace NBP-Bohunice

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 at the Laboratory from the Laboratory Manager.

Examinations:

Ordinal number	Examination procedure name	Examination procedure identification	Examined object
823 – Pathology Laboratory			
1.	Histological examination of tissues and diagnostics	SOPV-01	Tissues
2.	Peroperational examination of cells and tissues and diagnostics	SOPV-02	Tissues and cells
3.	Immunohistochemical examination of tissues (antigens) [a)]	SOPV-03	Tissues and cells
4.	Cytological examination and diagnostics	SOPV-04a	Cells from puncture of tissue, body fluids and pathological cavity content
5.	Cervicovaginal cytological examination and diagnostics	SOPV-04b	Cells from cervix, vagina and vulva
6.	Analysis of histological and cytological samples by in-situ hybridization method [b)]	SOPV-05	Tissues and cells
7.	Analysis of mutation status of genes by real-time PCR method [c)]	SOPV-06	Tissues, cells, blood
8.	Comprehensive genomic profiling by massively parallel sequencing method [d), e)]	SOPV-07	Tissues, cells
9.	Mutation analysis of genes by Sanger sequencing method [f)]	SOPV-08	Tissues, cells

Annex:
Flexible scope of accreditation

Examination procedure ordinal numbers:
3, 6, 7, 8, 9

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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.

Specification of the scope of accreditation:

a) List of antibodies for examination of antigens (method SOPV 03)

Examination name	Abbreviation used
α-1-antitrypsin	α1AT
α-1-fetoprotein	α1FP
Amyloid A	AA
Smooth muscle actin	SMA
Muscle-specific actin	MSA
ALK	ALK
AR	AR
ATRX	ATRX
β-catenin	β-catenin
β-HCG	β-HCG
Ber-EP4	Ber-EP4
Bcl-2	Bcl-2
Bcl-6	Bcl-6
CA-125	CA-125
Calcitonin	Calcit
Caldesmon	Caldesmon
Calponin-1	CALP-1
Calretinin	Calret
CD 1a	CD 1a
CD 3	CD 3
CD 4	CD 4
CD 5	CD 5
CD 7	CD 7
CD 8	CD 8
CD 10	CD 10
CD 15	CD 15
CD 19	CD 19
CD 20	CD 20
CD 21	CD 21
CD 23	CD 23
CD 25	CD 25
CD 30	CD 30
CD 31	CD 31
CD 34	CD 34
CD 43	CD 43
CD 45 (LCA)	CD 45 (LCA)
CD 45RO	CD 45RO
CD 56	CD 56
CD 57	CD 57
CD 68 (KP1)	CD 68
CD 68 (PG-M1)	CD 68 (PG-M1)

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Examination name	Abbreviation used
CD 79a	CD 79a
CD 99	CD 99
CD 117 (c-kit)	CD 117
CD 138	CD 138
CD 163	CD 163
CDX2	CDX2
CEA	CEA
CK AE1/3	CK AE1/3
CK HMW	CK HMW
CK 5/6	CK 5/6
CK 7	CK 7
CK 8	CK 8
CK 8/18	CK 8/18
CK 14	CK 14
CK 18	CK 18
CK 19	CK 19
CK 20	CK 20
CMV	CMV
c-MYC	c-MYC
Collagen IV	Collagen IV
Cyclin D1	Cyclin D1
Desmin	Desmin
DOG-1	DOG-1
E-cadherin	E-cadherin
EBV (LMP-1)	EBV
EGFR	EGFR
EMA	EMA
ER	ER
F VIII	F VIII
F XIIIa	F XIII
FLI-1	FLI-1
Galectin 3	Galectin 3
GATA3	GATA3
GAB1	GAB1
Gastrin	Gastrin
GFAP	GFAP
Glycophorin A	Glycophorin A
Glypican-3	Glypican-3
Granzym	Granzym
GS	GS
Histone H3.3 K27M	H3K27M
Trimethyl-Histone 3	TMH3
HBME-1	HBME-1
HCL	HCL
HE-4	HE-4
Hepatocytes	Hepatocytes

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Examination name	Abbreviation used
Her2/neu	Her2
HHV-8	HHV-8
HMB-45	HMB-45
HNF1 beta	HNF1
HP	HP
Chromogranin	Chromo
IDH-1	IDH-1
IDO 1	IDO 1
IgA	IgA
IgG	IgG
IgG4	IgG4
IgM	IgM
Inhibin	Inhibin
INI-1	INI-1
Kappa	Kappa
Ki-67	Ki-67
L-FABP (Liver-FABP)	L-FABP
LAG-3 (CD 223)	LAG3
L1CAM (CD171)	L1CAM
Lambda	Lambda
Laminin	Laminin
Langerin	Langerin
Lysozyme	Lysozyme
Mammaglobin	Mammaglobin
Melan A	Melan A
Mitochondria	Mitochondria
MLH1	MLH1
MSH2	MSH2
MSH6	MSH6
MUC4	MUC4
MUM-1	MUM-1
Myeloperoxidase	Myeloper
MYD 88	MYD88
MyoD1	MyoD1
Myogenin	Myogenin
Napsin A	Napsin A
NeuN	NeuN
NF	NF
NKX 2.2	NKX 2.2
NSE	NSE
Oct-3/4	Oct3/4
Olig 2	Olig2
OTX2	OTX2
p16	p16
p40	p40
p53	p53

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Examination name	Abbreviation used
p57	p57
p63	p63
PARK7/DJ1	PARK7/DJ1
PAX-5	PAX-5
PAX-8	PAX-8
PDL-1	PDL-1
Perforin	Perforin
PLAP	PLAP
PMS2	PMS2
Podoplanin (D240)	Podop
PR	PR
PSA	PSA
PSAP	PSAP
PTEN	pTEN
ROS1	ROS1
S-100	S-100
SALL4	SALL4
SOX 10	SOX 10
SOX 11	SOX 11
Synaptophysin	Synap
TdT	TdT
Thyroglobulin	Tg
TRAP	TRAP
TTF-1	TTF-1
Vimentin	Vim
WT-1	WT-1
YAP 1	YAP 1
75-NGFR	NGFR

b) List of probes used for ISH (SOPV-05)

FISH examination	Abbreviation used
Detection of ERBB2 gene amplification	ERBB2
Detection of ERBB2 gene amplification (reflex probe)	D17S122
Detection of 2p23 aberration (ALK-EML4 gene alteration/inversion)	ALK
Detection of 6q22.1 aberration (break in the ROS1 gene region)	ROS1
Detection of translocation t(8;14) - Burkitt's lymphoma	BL t(8;14)
Detection of translocation t(14;18) - Follicular lymphoma	FL t(14;18)

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Detection of translocation t(11;14) - Mantle-Cell lymphoma	MCL t(11;14)
Detection of 8q24 aberration (BL – break in the MYC gene region)	BL 8q24
Detection of 18q21.33 aberration (FL – break in the BCL2 gene region)	FL 18q21.33
Detection of 18q21 aberration (break in the MALT1 gene region)	MALT1
Detection of 3q27.3 aberration (break in the BCL6 gene region)	BCL6
Detection of CDKN2A gene deletion	CDKN2A
Detection of 1p36 aberration	1p36
Detection of 19q13 aberration	19q13
Detection of MYC gene amplification	MYC
Detection of EGFR gene amplification and chr 7 polysomy	EGFR/CEN7
Detection of ch 10 monosomy	CEN 10
Detection of 22q12.2 aberration (break in the EWSR1 gene region)	EWSR1
Detection of 17p13.2 aberration (break in the USP6 gene region)	USP6
Detection of MYCN gene amplification	MYCN
Determination of HER2 gene status	HER2-SISH
Detection of Epstein-Barr virus (EBER)	EBER

c) List of genes examined by real-time PCR method (SOPV-06)

Examination type	**Range / region of analysis**
Analysis of EGFR gene mutation status	42 mutations / Exons 18, 19, 20, 21 29 mutations / Exons 18, 19, 20, 21
Analysis of KRAS gene mutation status	19 mutations / Exons 2, 3, 4 (codons 12, 13, 59, 61, 117, 146)
Analysis of NRAS gene mutation status	16 mutations / Exons 2, 3, 4 (codons 12, 13, 59, 61, 117, 146)
Analysis of BRAF gene mutation status	7 mutations / Exons 15 (codon 600)

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d) List of analysed markers - DNA panel (SOPV-07)

ABL1	*AURKB*	*BTG1*	*CDKN2A*	*DCUN1D1*	*ERBB2*	*FANCF*	*FLCN*
ABL2	*AXIN1*	*BTK*	*CDKN2B*	*DDR2*	*ERBB3*	*FANCG*	*FLI1*
ACVR1	*AXIN2*	*C11orf30*	*CDKN2C*	*DDX41*	*ERBB4*	*FANCI*	*FLT1*
ACVR1B	*AXL*	*CALR*	*CEBPA*	*DHX15*	*ERCC1*	*FANCL*	*FLT3*
AKT1	*B2M*	*CARD11*	*CENPA*	*DICER1*	*ERCC2*	*FAS*	*FLT4*
AKT2	*BAP1*	*CASP8*	*CHD2*	*DIS3*	*ERCC3*	*FAT1*	*FOXA1*
AKT3	*BARD1*	*CBFB*	*CHD4*	*DNAJB1*	*ERCC4*	*FBXW7*	*FOXL2*
ALK	*BBC3*	*CBL*	*CHEK1*	*DNMT1*	*ERCC5*	*FGF1*	*FOXO1*
ALOX12B	*BCL10*	*CCND1*	*CHEK2*	*DNMT3A*	*ERG*	*FGF10*	*FOXP1*
ANKRD11	*BCL2*	*CCND2*	*CIC*	*DNMT3B*	*ERRFI1*	*FGF14*	*FRS2*
ANKRD26	*BCL2L1*	*CCND3*	*CREBBP*	*DOT1L*	*ESR1*	*FGF19*	*FUBP1*
APC	*BCL2L11*	*CCNE1*	*CRKL*	*E2F3*	*ETS1*	*FGF2*	*FYN*
AR	*BCL2L2*	*CD274*	*CRLF2*	*EED*	*ETV1*	*FGF23*	*GABRA6*
ARAF	*BCL6*	*CD276*	*CSF1R*	*EGFL7*	*ETV4*	*FGF3*	*GATA1*
ARFRP1	*BCOR*	*CD74*	*CSF3R*	*EGFR*	*ETV5*	*FGF4*	*GATA2*
ARID1A	*BCORL1*	*CD79A*	*CSNK1A1*	*EIF1AX*	*ETV6*	*FGF5*	*GATA3*
ARID1B	*BCR*	*CD79B*	*CTCF*	*EIF4A2*	*EWSR1*	*FGF6*	*GATA4*
ARID2	*BIRC3*	*CDC73*	*CTLA4*	*EIF4E*	*EZH2*	*FGF7*	*GATA6*
ARID5B	*BLM*	*CDH1*	*CTNNA1*	*EML4*	*FAM123B*	*FGF8*	*GEN1*
ASXL1	*BMPR1A*	*CDK12*	*CTNNB1*	*EP300*	*FAM175A*	*FGF9*	*GID4*
ASXL2	*BRAF*	*CDK4*	*CUL3*	*EPCAM*	*FAM46C*	*FGFR1*	*GLI1*
ATM	*BRCA1*	*CDK6*	*CUX1*	*EPHA3*	*FANCA*	*FGFR2*	*GNA11*
ATR	*BRCA2*	*CDK8*	*CXCR4*	*EPHA5*	*FANCC*	*FGFR3*	*GNA13*
ATRX	*BRD4*	*CDKN1A*	*CYLD*	*EPHA7*	*FANCD2*	*FGFR4*	*GNAQ*
AURKA	*BRIP1*	*CDKN1B*	*DAXX*	*EPHB1*	*FANCE*	*FH*	*GNAS*
GPR124	*ICOSLG*	*KLHL6*	*MLL*	*NSD1*	*PIK3R3*	*RAD51D*	*SH2D1A*
GPS2	*ID3*	*KMT2B*	*MLLT3*	*NTRK1*	*PIM1*	*RAD52*	*SHQ1*
GREM1	*IDH1*	*KMT2C*	*MPL*	*NTRK2*	*PLCG2*	*RAD54L*	*SLIT2*
GRIN2A	*IDH2*	*KMT2D*	*MRE11A*	*NTRK3*	*PLK2*	*RAF1*	*SLX4*
GRM3	*IFNGR1*	*KRAS*	*MSH2*	*NUP93*	*PMAIP1*	*RANBP2*	*SMAD2*
GSK3B	*IGF1*	*LAMP1*	*MSH3*	*NUTM1*	*PMS1*	*RARA*	*SMAD3*
H3F3A	*IGF1R*	*LATS1*	*MSH6*	*PAK1*	*PMS2*	*RASA1*	*SMAD4*
H3F3B	*IGF2*	*LATS2*	*MST1*	*PAK3*	*PNRC1*	*RB1*	*SMARCA4*
H3F3C	*IKBKE*	*LMO1*	*MST1R*	*PAK7*	*POLD1*	*RBM10*	*SMARCB1*
HGF	*IKZF1*	*LRP1B*	*MTOR*	*PALB2*	*POLE*	*RECQL4*	*SMARCD1*
HIST1H1C	*IL10*	*LYN*	*MUTYH*	*PARK2*	*PPARG*	*REL*	*SMC1A*
HIST1H2BD	*IL7R*	*LZTR1*	*MYB*	*PARP1*	*PPM1D*	*RET*	*SMC3*
HIST1H3A	*INHA*	*MAGI2*	*MYC*	*PAX3*	*PPP2R1A*	*RFWD2*	*SMO*
HIST1H3B	*INHBA*	*MALT1*	*MYCL1*	*PAX5*	*PPP2R2A*	*RHEB*	*SNCAIP*
HIST1H3C	*INPP4A*	*MAP2K1*	*MYCN*	*PAX7*	*PPP6C*	*RHOA*	*SOCS1*
HIST1H3D	*INPP4B*	*MAP2K2*	*MYD88*	*PAX8*	*PRDM1*	*RICTOR*	*SOX10*
HIST1H3E	*INSR*	*MAP2K4*	*MYOD1*	*PBRM1*	*PREX2*	*RIT1*	*SOX17*
HIST1H3F	*IRF2*	*MAP3K1*	*NAB2*	*PDCD1*	*PRKAR1A*	*RNF43*	*SOX2*

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HIST1H3G	*IRF4*	*MAP3K13*	*NBN*	*PDCD1LG2*	*PRKCI*	*ROS1*	*SOX9*
HIST1H3H	*IRS1*	*MAP3K14*	*NCOA3*	*PDGFRA*	*PRKDC*	*RPS6KA4*	*SPEN*
HIST1H3I	*IRS2*	*MAP3K4*	*NCOR1*	*PDGFRB*	*PRSS8*	*RPS6KB1*	*SPOP*
HIST1H3J	*JAK1*	*MAPK1*	*NEGR1*	*PDK1*	*PTCH1*	*RPS6KB2*	*SPTA1*
HIST2H3A	*JAK2*	*MAPK3*	*NF1*	*PDPK1*	*PTEN*	*RPTOR*	*SRC*
HIST2H3C	*JAK3*	*MAX*	*NF2*	*PGR*	*PTPN11*	*RUNX1*	*SRSF2*
HIST2H3D	*JUN*	*MCL1*	*NFE2L2*	*PHF6*	*PTPRD*	*RUNX1T1*	*STAG1*
HIST3H3	*KAT6A*	*MDC1*	*NFKBIA*	*PHOX2B*	*PTPRS*	*RYBP*	*STAG2*
HLA-A	*KDM5A*	*MDM2*	*NKX2-1*	*PIK3C2B*	*PTPRT*	*SDHA*	*STAT3*
HLA-B	*KDM5C*	*MDM4*	*NKX3-1*	*PIK3C2G*	*QKI*	*SDHAF2*	*STAT4*
HLA-C	*KDM6A*	*MED12*	*NOTCH1*	*PIK3C3*	*RAB35*	*SDHB*	*STAT5A*
HNF1A	*KDR*	*MEF2B*	*NOTCH2*	*PIK3CA*	*RAC1*	*SDHC*	*STAT5B*
HNRNPK	*KEAP1*	*MEN1*	*NOTCH3*	*PIK3CB*	*RAD21*	*SDHD*	*STK11*
HOXB13	*KEL*	*MET*	*NOTCH4*	*PIK3CD*	*RAD50*	*SETBP1*	*STK40*
HRAS	*KIF5B*	*MGA*	*NPM1*	*PIK3CG*	*RAD51*	*SETD2*	*SUFU*
HSD3B1	*KIT*	*MITF*	*NRAS*	*PIK3R1*	*RAD51B*	*SF3B1*	*SUZ12*
HSP90AA1	*KLF4*	*MLH1*	*NRG1*	*PIK3R2*	*RAD51C*	*SH2B3*	*SYK*
TAF1	*TERT*	*TGFBR2*	*TOP2A*	*TSC2*	*WISP3*	*YES1*	*ZRSR2*
TBX3	*TET1*	*TMEM127*	*TP53*	*TSHR*	*WT1*	*ZBTB2*	
TCEB1	*TET2*	*TMPRSS2*	*TP63*	*U2AF1*	*XIAP*	*ZBTB7A*	
TCF3	*TFE3*	*TNFAIP3*	*TRAF2*	*VEGFA*	*XPO1*	*ZFHX3*	
TCF7L2	*TFRC*	*TNFRSF14*	*TRAF7*	*VHL*	*XRCC2*	*ZNF217*	
TERC	*TGFBR1*	*TOP1*	*TSC1*	*VTCN1*	*YAP1*	*ZNF703*	

e) List of analysed markers - RNA panel (SOPV-07)

RNA FUSION			**RNA SPLICE VARIANTS**
ABL1	*ETV5*	*NOTCH2*	*AR*
AKT3	*EWSR1*	*NOTCH3*	*EGFR*
ALK	*FGFR1*	*NRG1*	*MET*
AR	*FGFR2*	*NTRK1*	
AXL	*FGFR3*	*NTRK2*	
BCL2	*FGFR4*	*NTRK3*	
BRAF	*FLI1*	*PAX3*	
BRCA1	*FLT1*	*PAX7*	
BRCA2	*FLT3*	*PDGFRA*	
CDK4	*JAK2*	*PDGFRB*	
CSF1R	*KDR*	*PIK3CA*	
EGFR	*KIF5B*	*PPARG*	

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RNA FUSION			**RNA SPLICE VARIANTS**
EML4	*KIT*	*RAF1*	
ERBB2	*MET*	*RET*	
ERG	*MLL*	*ROS1*	
ESR1	*MLLT3*	*RPS6KB1*	
ETS1	*MSH2*	*TMPRSS2*	
ETV1	*MYC*		
ETV4	*NOTCH1*		

f) List of markers examined by the Sanger sequencing method (SOPV- 08**)**

Examined markers	**Reference sequences**	**Region of analysis**
H3-3A (H3F3A)	NM_002107	Exon 2 (codons 28, 34)
H3C2 (HIST1H3B)	NM_003537	codon 28
H3C3 (HIST1H3C)	NM_003531	codon 28
IDH1	NM_005896	Exon 4 (codon 132)
IDH2	NM_002168	Exon 4 (codon 172)
POLE	NM_006231	Exons 9, 10, 11, 12, 13, 14
TERT	NM_198253	Promoter (region c.-124 and c.-146)

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2. **Workplace NBP-Maternity Hospital**

Ordinal number	Examination procedure name	Examination procedure identification	Examined object
823 – Pathology Laboratory			
1.	Histological examination of tissues and diagnostics	SOPV-01	Tissues
2.	Peroperational examination of cells and tissues and diagnostics	SOPV-02	Tissues and cells
3.	Reserved		
4.	Cytological examinations and diagnostics	SOPV-04a	Cells from puncture of tissue, body fluids and pathological cavity content
5.	Cervicovaginal cytological examination and diagnostics	SOPV-04b	Cells from cervix, vagina and vulva

3. **Workplace DN**

Ordinal number	Examination procedure name	Examination procedure identification	Examined object
823 – Pathology Laboratory			
1.	Histological examination of tissues and diagnostics	SOPV-01	Tissues
2.	Peroperational examination of cells and tissues and diagnostics	SOPV-02	Tissues and cells