

## **MOLECULAR ONCOLOGY & ASSOCIATED BIOMARKERS REQUISITION**

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PATIENT INFORMATION (PLEASE PRINT IN BLAC	K INK)		CL	IENT INFORMATION
Last Name	First	MI		
Address	Birth Date (MM/DD/YYYY)	Sex □ M □ F		
City	SS # International Pat	tient?		
State Zip	Home Phone			
Hospital/Physician Office Patient ID #	Accession #		ORDERING PHYSICIAN	CONTACT
MEDICAL NECESSITY NOTICE: When ordering tests for which	n Medicare reimbursement will be sought, physicians (or other		Choose one:	
	necessary for the diagnosis or treatment of a patient, rather t	than for screening purposes.	Physician Name	
INSURANCE BILLING INFORMATION (PLEASE	E ATTACH CARD OR PRINT IN BLACK INK)		NPI #	
	Insurance (Complete insurance information below)	□ Patient	Physician Phone	
PATIENT STATUS: ☐ Inpatient ☐ Outpatient ☐ N	Non-Hospital Patient Hospital discharge date:/_	/	,	
PRIMARY: ☐ Medicare ☐ Medicaid (Ohio only) [	□ Other Ins. □ Self		Physician Email	
				_)
Subscriber Last Name	First	MI		)
			SPECIMEN INFORMAT	
Beneficiary / Member #	Group #		., .	ical Pathology report with requisitions
Claims Address	City State			):/
SECONDARY: □ No □ Yes (if Yes, please attach)	ABN: □ No □ Yes	Σίβ	Body Site:	Client Case #: AM PM
DIAGNOSIS CODE (REQUIRED) ICD-10 Codes 1.		2	Specimen ID:	
		·	☐ Paraffin Cell Blocks:	Paraffin Tissue Blocks:
ADDITIONAL CLINICAL INFORMATION			☐ Slides, unbaked & unstain	
			Fixation Type:  Formali  **Decalcified specimens will l	n
			Breast Samples: CAP/ASCO Re	•
			10% neutral buffered formalin:	☐ Yes ☐ No ☐ Unknown
			Fixation time $>$ 6 and $<$ /2 hour Cold ischemic time $\le 1$ hour:	rs:
AVAILABLE MOLECULAR AND BIOMARKER	TESTING WITH INTERPRETATION:			
NEXT-GENERATION SEQUENCING (NGS) PANELS	ENDOMETRIAL/GYN (CONTINUED)	LYMPHOMA		SOFT TISSUE/SARCOMA
CC-SIGN® NTRK 1,2,3, by NGS (as part of NTRK Plus Gene Fusion NGS Panel)	☐ PD-L1 by IHC (Clone 22C3) — for cervical primary only ☐ <i>MLH1</i> promoter methylation (PCR) <i>MLH1PH</i>	<ul> <li>□ B-Cell Clonality BIOMED-2 (PCI</li> <li>□ B-Cell Immunoglobulin Heavy (</li> </ul>		□ CC-SIGN® TOP NGS Panel includes MYC amplification, KIT, BRAF, PDGFRA, GNAS, GNAQ,
☐ CC-SIGN® Targeted Oncology Panel (TOP) by NGS for pan	GASTROINTESTINAL STROMAL TUMOR	☐ B-Cell Immunoglobulin Kappa (		GNA11, H3-3A/B, CTNNB1 + pan cancer markers  □ CC-SIGN® Solid Tumor Gene Fusion NGS Panel
cancer hotspots, copy number gains & fusions 59 driver genes; refer to TOP Gene List on Test Directory	☐ CC-SIGN® TOP NGS Panel includes BRAF, KIT, PDGFRA + pan cancer markers	☐ FISH for DUSP22 IRF4 ☐ T-Cell Clonality (TCRB & TCRG r	rearrangement\ (DCD) TCDMD0	(59 gene panel) — refer to SRCNGS gene list on Test Directory
☐ FFPE TOPTO ☐ Alcohol- or FFPE-fixed cell blocks TOPCY	GENITOURINARY	☐ T-Cell Receptor Beta (TCRB) Bli		FISH (select any/all):  DDIT3 (CHOP)/GLI1 (12q13) DDIT3
OTHER	☐ CC-SIGN® TOP NGS Panel includes AR, TP53, TMPRSS2::ERG, TMPRSS2::ETV1,	☐ T-Cell Receptor Gamma (TCRG)		□ FOXO1A (13q14) FKHR □ FUS (16p11) FUS
☐ BRAF V600E by ddPCR BRAFO ☐ KIT D816V by ddPCR K8160	TMPRSS2::ETV4, TMPRSS2::ETV5, SLC45A3::ERG, SLC45A3::BRAF, FGFR3::TACC3 + pan cancer markers	Immunohistochemistry/CISH (select  □ PD-L1 (Clone 22C3)	ct any/all):	☐ MDM2 amplification MDM2
☐ EGFR Hotspot by PCR EGFRID	☐ Mismatch repair (MMR) by IHC	FISH (select any/all):		☐ MYC amplification (angiosarcoma) MYCAMP ☐ SS18 (18q11) SYT
☐ KRAS Hotspot by PCR KRASID	(reflex to <i>MLH1</i> promoter methylation)  ☐ PD-L1 by IHC for pembrolizumab/Keytruda®	☐ Aggressive B-cell Lymphoma BCL6, IGH::MYC, t(8;14)) FABC		STOMACH/EGJ
BREAST  □ CC-SIGN® TOP NGS Panel includes ESR1/ER, ERBB2/HER2, AKT1,	use (Clone 22C3)		□ BCL6 BCL6FT	CC-SIGN® TOP NGS Panel includes TP53, ERBB2/HER2 amplification, NTRK fusions + pan
PIK3CA, CCND1, ETV6::NTRK3, MAGI3::AKT3, FGFR2::AFF3 + pan cancer markers	HEAD & NECK AND THYROID  □ CC-SIGN® TOP NGS Panel	☐ BIRC::MALT T1118 ☐ IGH::CCND1 t(11;14) T1114	☐ IGH::BCL2 T1418 □ IGH::MYC T814	cancer markers  Stomach/EGJ Profile: Mismatch repair (MMR) by IHC, HER2
☐ Breast Markers Profile: ER, PR, HER2 by IHC (reflex to FISH if equivocal)	includes BRAF, RAS genes, TP53, pTERT, MET, PIK3CA, RET/ALK/ BRAF fusions, PAX8::PPARG + pan cancer markers	□ MALT MALT1 □ MYC am	plification MYCAMP	by IHC (reflex to FISH in equivocal cases), PD-L1 by IHC (Clone 22C3)
Immunochemistry (select any/all):	☐ CC-SIGN® Head & Neck Gene Fusion NGS Panel	MELANOMA  □ CC-SIGN® TOP NGS Panel		☐ Mismatch repair (MMR) by IHC
☐ ER ☐ PR ☐ Androgen Receptor ☐ Ki67 ☐ HER2 (reflex to FISH if equivocal)	☐ HER2 by IHC (reflex to FISH in equivocal cases) ☐ HPV High and Low Risk by in situ hybridization	includes BRAF, KIT, NRAS, pTEF	RT + pan cancer markers	(reflex to <i>MLH1</i> promoter methylation)  ☐ HER2 by IHC (reflex to FISH in equivocal cases)
☐ HER2 by FISH (reflex to IHC if Group 2, 3, or 4)	☐ HPV High Risk by in situ hybridization	☐ BRAF V600E by IHC ☐ Cutaneous Melanoma (FISH) C	MFISH	□ PD-L1 by IHC (Clone 22C3)
☐ Mismatch repair (MMR) by IHC (reflex to MLH1 promoter methylation)	☐ HPV Low Risk by in situ hybridization☐ NUT by IHC	☐ PD-L1 by IHC (Clone 22C3)		OTHER TESTING  ☐ C4d by IHC
□ PD-L1 by IHC (Clone 22C3)  COLORECTAL/SMALL BOWEL	□ PD-L1 by IHC (Clone 22C3)	NEURO  ☐ CC-SIGN® TOP NGS Panel		☐ HPV High and Low Risk by <i>in situ</i> hybridization
☐ CC-SIGN® TOP NGS Panel includes BRAF, KRAS, NRAS, PIK3CA, ERBB2/HER2 + pan cancer markers	LUNG		FR, PDGFRA, PIK3CA, EGFR vIII,	☐ HPV High Risk only by <i>in situ</i> hybridization ☐ HPV Low Risk only by <i>in situ</i> hybridization
☐ Metastatic Colorectal/Small Bowel Profile: Mismatch	CC-SIGN® TOP NGS Panel includes BRAF, EGFR, ERBB2/HER2, KRAS, MET, DDR2, MET	cancer markers	·	☐ Microsatellite instability (PCR) MSICCT
repair (MMR) by IHC (reflex to <i>MLH1</i> promoter methylation), CC-SIGN TOP NGS Panel	exon 14 skipping ALK/RET/ROS1 fusions + pan cancer markers  Lung Carcinoma (non-squamous NSCLC) Profile:	<ul> <li>☐ Glioma panel (1p/19q/EGFR) (F</li> <li>☐ 1p/19q (FISH) 1P19Q</li> </ul>	-ISH)	must provide normal + tumor representative specimen  Mismatch repair (MMR) by IHC
☐ Mismatch repair (MMR) by IHC (reflex to <i>MLH1</i> promoter methylation)	ALK D5F3 by IHC (reflex to FISH), PD-L1 by IHC (Clone 22C3), ROS1 by FISH, RET by FISH, CC-SIGN TOP NGS Panel	☐ EGFR (FISH) EGFRF	_	(reflex to MLH1 promoter methylation)
☐ HER2 by IHC (reflex to FISH in equivocal cases)	☐ ALK (FISH) FSHLNG	☐ MGMT Methylation (PCR) MGM PANCREATICOBILIARY	T	☐ MLH1 promoter methylation (PCR) MLH1PH  ONCOLOGY FISH: REFER TO ONCOLOGY FISH PROBE LIST
☐ MLH1 promoter methylation (PCR) MLH1PH	□ RET (FISH) RET □ ROS (FISH) ROS1	□ CC-SIGN® TOP NGS Panel		Indicate probe(s):
ENDOMETRIAL/GYN  □ CC-SIGN® TOP NGS Panel includes ERBB2/HER2, PIK3CA,	☐ ROS (FISH) ROS1 ☐ ALK D5F3 by IHC (reflex to FISH)		NAS, NRAS, pTERT, ERBB2/HER2, RK fusions + pan cancer markers	
AKT1, CTNNB1, TP53, NTRK fusions + pan cancer markers	□ PD-L1 by IHC (Clone 22C3)		•	
☐ Mismatch repair (MMR) by IHC (reflex to MLH1 promoter methylation) ☐ ER bv IHC ☐ PR bv IHC ☐ HER2 bv IHC	□ NUT by IHC			

## **FISH Panels**

	Probes included		Accepted Specimen Sources				
PANEL NAME	QTY	Target Locations	Blood	Bone Marrow	FFPET	Cell Block*	
Aggressive B-Cell Lymphoma	4	BCL2, BCL6, MYC, IGH::MYC	Х	х	Х		
Acute Myeloid Leukemia	4	PML::RARA, RUNX1::RUNX1T1, CBFB::MYH11, MLL	х	х			
B Lymphoblastic Leukemia	6	BCR::ABL, CRLF2, CRLF2::IGH, ETV6::RUNX1, MLL, Trisomy 4/10	Х	х			
CLL	3	CLL1, CLL2, IGH::CCND1	Х				
Cutaneous Melanoma	5	RREB1, CCND1, MYB, MYC, CDKN2A			Х		
Glioma	3	1p36, 19q13, EGFR			Х		
Myelodysplastic Syndrome	3	5q, 7q, 20q, CEP 8	Х	х			
Myeloproliferative Neoplasms	4	BCR::ABL , PDGFRA, PDGFRB, FGFR1	Х	х			
Plasma Cell Myeloma	5**	RB1/TP53, CKS1B/CDKN2C, CEP 9/CEP 15, IGH, IGH::CCND1 **Reflex to IGH::MMSET and IGH::MAF if indicated.*		х			
UroVysion	4	CEP 3, CEP 7, CEP 17, 9p21	Thin prep	slide			

 $<sup>{}^\</sup>star \text{Must}$  be formalin fixed. Alcohol fixed cell blocks will be rejected.

## FISH Single Target

PROBE NAME	Chromosomal / Target Location	Blood	Bone Marrow	FFPET	Cell Block*	Thin Prep Slide
1p	1p36			х		
5q	5p15/5q31	Х	Х			
7q	CEP7/7q31	Х	Х			
19q	19q13			Х		
20q	20q12 Only offered with CEP 8	Х	х			
ALK for NSCLC	2p23			Х	Х	Х
BCL2	18q21	Х	Х	Х		
BCL6	3q27	Х	Х	Х		
BCRABL	t(9;22)(q34;q11.2)	Х	х			
BIRC3::MALT	t(11;18)(q22;q21)			х		
CBFB::MYH11	16q22-Inversion 16	Х	Х			
CDKN2A	9p21 Only offered as part of Cutaneous Melanoma & UroVysion Panels			Х		х
CCND1	11q13	Х	Х	Х		
CEP 3	Centromere of chromosome 3 Only offered as part of Urovysion Panel					х
CEP 4	Centromere of chromosome 4 Only offered with CEP 10	Х	х			
CEP 7	Centromere of chromosome 7 Only offered as part of Urovysion Panel					х
CEP 8	Centromere of chromosome 8 Only offered with 20q	Х	х			
CEP 9	Centromere of chromosome 9 Only offered as part of Plasma Cell Myeloma Panel		х			
CEP 10	Centromere of chromosome 10 Only offered with CEP 4	Х	Х			
CEP 15	Centromere of chromosome 15 Only offered as part of Plasma Cell Myeloma Panel		Х			
CEP 17	Centromere of chromosome 17 Only offered as part of Urovysion Panel					х

PROBE NAME	Chromosomal / Target Location	Blood	Bone Marrow	FFPET	Cell Block*	Thin Prep Slide
CEP X	Centromere of X chromosome Only offered with CEP Y (DXY3)	Х				
CEP Y (DXY3)	Centromere of Y chromosome Only offered with CEP X	Х				
CEP Y (DZY1)	Yqh of Y Chromosome	Х				
CHOP/DDIT3	12q13			Х		
CKS1B/CDKN2C	1p31,1q21 Only offered as part of Plasma Cell Myeloma Panel		x			
CLL1	17p13,11q22 Only offered as part of CLL Panel	Х	Х			
CLL2	D13S319/CEP 12/13q24 Only offered as part of CLL Panel	Х	х			
EGFR	7p11.2			Х		
ETV6::RUNX1	t(12;21)(p13;q22)	Х	Х			
EWSR1	22q12			Х		
FGFR1	8p12	Х	х			
FOX01	13q14			Х		
FUS	16p11.2			х		
HER2	17q12			Х		
IGH	14q23	Х	Х	Х		
IGH::BCL2	t(14;18)(q32;q21)	Х	х	Х		
IGH::CCND1	t(11;14)(q13;q32)	Х	х	Х		
IGH::MAF	t(14;16)(q32;q23) Only offered as part of Plasma Cell Myeloma Panel		x			
IGH::MMSET	t(4;14)(p16q32) Only offered as part of Plasma Cell Myeloma Panel		х			
IGH::MYC	t(8;14)(q24;q32)	Х	Х	Х		
MALT1	18q21			Х		
MDM2	12q15			Х		
MLL	11q23	Х	Х			
MYB	6q23 Only offered as part of Cutaneous Melanoma Panel			Х		
MYC-Break apart	8q24	Х	х	Х		
MYC-Amplification	8q24			х		
PDGFRA	4q12	Х	х			
PDGFRB	5q32	Х	Х			
PML::RARA	t(15;17)(q22;q21)	Х	х			
RARA	17q21	Х	х			
RB1/TP53	13q/17p Only offered as part of Plasma Cell Myeloma Panel		х			
RET	10q11.21			Х	Х	
ROS1	6q22			х	Х	
RREB1	6p25 Only offered as part of Cutaneous Melanoma Panel			Х		
RUNX1::RUNX1T1	t(8;21)(q21;q22)	Х	х			
SRY	Yp11.3	Х				
SS18::SYT	t(X;18)(p11;q11)			Х		
XIST	Xq13.2	Х				