

ATTACH THE FOLLOWING
 Signed Requisition
 Pathology Report
 Insurance Sheet and Front and Back Copy of Card
 Initial Clinical Note
 Most Recent Progress Note

PATIENT INFORMATION				
Last Name	First Name	MI	DOB	Gender <input type="checkbox"/> M <input type="checkbox"/> F
Street Address		Apt. #	Phone	
City	State	Postal Code	Country	

ORDERING PHYSICIAN INFORMATION			
Physician	Office / Practice / Institution	Email	
Street Address		Phone	Fax
City	State	Postal Code	Country
Office Contact Name	Office Contact Phone	Office Contact Email	

ADDITIONAL PHYSICIAN TO BE COPIED			
Physician	Email	Phone	Fax

PATHOLOGY INFORMATION				
Office / Practice / Institution			Phone	Fax
Street Address	City	State	Postal Code	Country

SPECIMEN INFORMATION			
Primary Tumor Type (eg: Bladder, Breast, Lung)	Pathology Dx/Histology (eg: Adenocarcinoma, Squamous)	<input type="checkbox"/> Current Pathology Report Included/Attached	
Anatomic Collection Site	Collection Date	Case/Specimen	
FFPE Specimen Type: <input type="checkbox"/> Block <input type="checkbox"/> Slides <input type="checkbox"/> Shaves/Curls # _____ thickness: _____ & H&E slide <input type="checkbox"/> Physician's office will arrange for specimen shipping.			

TESTING OPTIONS (PLEASE SELECT THE BOXES)	
<input type="checkbox"/> PARADIGM CANCER DIAGNOSTIC (PCDx) – Comprehensive Genomic Profiling (CGP) Test including DNA, RNA, and IHCs Breast Cancer: IHCs – AR, MMR, PD-L1 (22C3), TOPO1, TP, TRKpan Colon Cancer: IHCs – HER2, MMR, PD-L1 (22C3), TRKpan NSCLC: IHCs – hENT1, MET, MMR, PD-L1 (22C3), TOPO1, TRKpan and Fusion Panel Other Solid Tumor: IHCs – hENT1, HER2, MMR, PD-L1 (22C3), TRKpan Notes: Mismatch Repair (MMR) IHCs include: MLH1, MSH2, MSH6 and PMS2	IHC biomarkers to run in addition to tumor specific PCDx panel: <input type="checkbox"/> ALK <input type="checkbox"/> HER2/neu <input type="checkbox"/> PD1 <input type="checkbox"/> ROS1 <input type="checkbox"/> TUBB3 <input type="checkbox"/> AR <input type="checkbox"/> IDO <input type="checkbox"/> PD-L1 (22C3) <input type="checkbox"/> TOPO1 <input type="checkbox"/> CAIX <input type="checkbox"/> MET <input type="checkbox"/> PR <input type="checkbox"/> TP <input type="checkbox"/> ER <input type="checkbox"/> MGMT <input type="checkbox"/> PTEN <input type="checkbox"/> TRKpan <input type="checkbox"/> hENT1 <input type="checkbox"/> MMR <input type="checkbox"/> RET <input type="checkbox"/> TS <input type="checkbox"/> Perform full panel of orderable IHC Biomarkers <input type="checkbox"/> Fusion Panel with PCDx <input type="checkbox"/> Sarcoma Fusion Panel with PCDx
<input type="checkbox"/> Include NGS Analysis (DNA and RNA) only	

BILLING INFORMATION			
BILL TO: <input type="checkbox"/> Insurance/Medicare (provide insurance sheet and front and back copy of card) <input type="checkbox"/> Client <input type="checkbox"/> Self/Cash Pay (Paradigm will contact) <input type="checkbox"/> Other _____	Primary Insurance	Policy Holder Name	
	Policy #	Group #	Policy Holder DOB
	Secondary Insurance	Policy Holder Name	
	Policy #	Group #	Policy Holder DOB

CONSENT AND CERTIFICATE OF MEDICAL NECESSITY
My signature is a Certificate of Medical Necessity by the treating physician that this testing has been explained and is authorized for the care of the patient and that consent has been obtained for Paradigm to release results as part of reimbursement, for follow up information to be obtained, and for the data to be de-identified and disclosed for quality assurance and research. Paradigm customer service may be contacted for any discounts if insurance does not fully cover and with any questions. Unless otherwise indicated, it is acknowledged that Paradigm may direct the testing selected based on the requisition and approach listed on the Paradigm website, according to the pathology reports, and status or quantity of the specimen received.

ICD-10 CODES
ICD-10 Codes are required for billing. When ordering tests for which reimbursement will be sought, only order tests that are medically necessary for the diagnosis and treatment of the patient.

NOTES OR INSTRUCTIONS

PHYSICIAN SIGNATURE	
Ordering Physician Signature	
Printed Name	Date

PARADIGM CANCER DIAGNOSTIC (PCDX™) – SPECIMEN REQUIREMENTS

Formalin Fixed Paraffin Embedded (FFPE) Samples

PCDX™ TESTING	SAMPLE TYPE	SPECIMEN REQUIREMENTS	TUMOR CONTENT		SAMPLE SIZE	
			OPTIMAL	MINIMAL	OPTIMAL	MINIMAL
NGS Analysis	Paraffin Block	(1) FFPE block from most recent surgery or biopsy, containing the most amount of tumor, excluding bone.	40%	5%	75 mm ³ (5 mm x 5 mm x 3 mm) or 4 to 6 needle biopsies	One (1) core needle with 10% tumor (10mm x 2mm x 1mm) RISK THAT FULL PROFILE CANNOT BE PERFORMED
	Shaves/Curls	(6-10) 10 micrometer thick freshly cut curls along with H&E stained section of same block.				
	Slides	(12-20) 4 or 5 micrometer unbaked, unstained slides, or (6-10) 10 micrometer unbaked, unstained slides.				
NGS Analysis & IHC	Paraffin Block	(1) FFPE block from most recent surgery or biopsy, containing the most amount of tumor, excluding bone.	40%	5%	75 mm ³ (5 mm x 5 mm x 3 mm) or 4 to 6 needle biopsies	One (1) core needle with 10% tumor (10mm x 2mm x 1mm) RISK THAT FULL PROFILE CANNOT BE PERFORMED
	Shaves/Curls & Unstained Slides	(6-10) 10 micrometer thick freshly cut curls along with H&E stained section of same block & (8-25) 4 micrometer, freshly cut, unstained, unbaked, sections on positively charged slides, or (1) Slide per IHC selected +1				

PARADIGM CUSTOMER SERVICE MAY CONTACT THE ORDERING PHYSICIAN OR PATHOLOGY IF THE SPECIMEN RECEIVED DOES NOT MEET TESTING REQUIREMENTS.

Testing Prioritization

If the specimen is insufficient to fulfill the complete analysis requested, unless otherwise indicated, the priority of testing will be NGS followed by IHC. If the specimen is insufficient for testing by NGS, then only IHC will be performed.

PARADIGM PCDx GENE LIST

DNA MUTATION

AKT1	ERBB4	IDH1	NRAS
ALK	ERCC2	IDH2	PDGFRA
BRAF	ERRF1	KIT	PIK3CA
BRCA1	ESR1	KRAS	PTCH1
BRCA2	FGFR2	MAP2K1	RET
CREBBP	FGFR3	MAP2K2	ROS1
CSF1R	FLT3	MAP3K1	SMO
DDR2	GATA3	MET	TGFBR2
EGFR	GNAQ	MSH6	TP53
EP300	GNAS	MSI*	TSC1
ERBB2	HRAS	MTOR	TSC2

COPY NUMBER VARIATION

19Q	CCND3	FGF3	MYCN
1P	CCNE1	FGF4	NTRK1
ALK	CDK4	FGFR1	SMAD4
AURKA	CDK6	FGFR2	TOP2A
C11ORF30	CDKN2A	FGFR3	VEGFA
CCND1	EGFR	MET	
CCND2	ERBB2	MYC	

mRNA EXPRESSION

AR	DCK	KIT	RELA
AREG	DHFR	LRP6	RPS6KB1
ARID1A	DPYD	MET	RRM1
BAD	EPHA2	MGMT	SLC29A1
BAX	ERBB2	MITF	SSTR2
BCL2	ERBB3	MTOR	TNFSF13
BIRC5	ERCC1	NFKB1	TOP2A
BRCA1	EREG	PARP1	TUBB3
CA9	ESR1	PDGFRB	TYMP
CDA	EZH2	PGR	TYMS
CDH1	FGFR1	PTEN	VEGFA
CES2	IGF1R	PTGS2	
CHUK	KDR	PTPN6	

PROTEIN EXPRESSION BY IHC

ALK**	IDO	PTEN	TS
AR	MET	RET	TUBB3
CAIX	MGMT	ROS1**	MLH1
ER	PD1	TOPO1	MSH2
HENT1	PDL1	TP	MSH6
HER2	PR	TRKpan***	PMS2

FUSION PANEL

SPLICE VARIANTS: EGFR VIII (Exon 2-7 Skipping Event) MET (Includes Exon 14 Skipping)			
FUSIONS:			
ALK	FGFR2	NTRK2	ROS1
AXL	FGFR3	NTRK3	THADA
BRAF	MET	PPARG	
CCND1	NGR1	RAF1	
FGFR1	NTRK1	RET	

SARCOMA FUSION PANEL

ALK	HMG2	SS18
CAMTA1	JAZF1	STAT6
CCNB3	MEAF6	TAF15
CIC	MKL2	TCF12
EPC1	NCOA2	TFE3
EWSR1	NTRK3	TFG
FOXO1	PDGFB	USP6
FUS	PLAG1	YWHA
GLI1	ROS1	

*Please insert in the notes section if the physician would like to include MSI testing by PCR with PCDx order.

**For NSCLC, if insufficient specimen for NGS.

***Fusion panel run if TRKpan IHC is positive.