

Test Requisition Form

Please Fax to 877-991-9720

Questions? 844-232-4719 or customerservice@paradigmdx.com



Patient Information

Name (Last, First, MI)			
DOB (MM/DD/YYYY)	☐ Female (XX) ☐ Male (XY)	Phone (primary)	
Street Address			
City	State	Postal code	Country (if not USA)

Ordering Physician Information

Physician Name / NPI #		Fax
Office/Practice/Institution		Email
Address		
Office Contact Name	Contact Phone	Contact Email

Pathology Information

Office/Practice/Institution ☐ TC/PC		
Address		
Email	Phone	Fax

Specimen Information

☐ NSCLC ☐ Other cancer type:		
Anatomic collection site	Collection Date	Specimen ID
Format submitted ☐ Slides ☐ FFPE block ☐ Curls	ICD-10 Codes	

Testing Options

- ☐ PCDx: 234 genes + immunotherapy + IHC Panel
☐ Immunotherapy: TMB + MMR + PD-L1 IHC

PCDx IHC Panels

Breast AR, PD-L1, TP, TOPO1, MMR, TRKpan
Colorectal MMR, PD-L1, TRKpan, HER2
NSCLC PD-L1, ALK, ROS1, hENT1, TRKpan, MMR
Other hENT1, HER2, MMR, PD-L1, TRKpan

IHCs will be cut in order listed until complete or block is exhausted
MMR requires 4 slides for MLH1, MSH2, MSH6 and PMS2

Individual IHCs

- | | |
|---|--|
| ☐ ALK
☐ AR
☐ CAIX
☐ ER
☐ hENT1
☐ HER2/neu
☐ IDO
☐ MET
☐ MGMT
☐ MMR
☐ PD1 | ☐ PD-L1
☐ PR
☐ PTEN
☐ RET
☐ ROS1
☐ TOPO1
☐ TP
☐ TRKpan
☐ TS
☐ TUBB3 |
|---|--|

Individual Molecular

- ☐ NGS (234 genes)
☐ TMB only (individual mutations not provided)

Billing Information

Bill to: ☐ Insurance/Medicare ☐ Self pay ☐ Client ☐ Other: _____		
Primary Insurance	Policy #	Group #
Primary Policy Holder		DOB
Secondary Insurance	Policy #	Group #
Secondary Policy Holder		DOB

Submission checklist

- ☐ Signed requisition (this form)
☐ Pathology report
☐ Insurance sheet
☐ Front/back of insurance card
☐ Initial clinical note
☐ Most recent progress note

Notes or instructions:

Certificate of medical necessity, consent, test authorization, and physician signature

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.

Ordering Physician Signature

Printed Name

____/____/____
Date (MM/DD/YYYY)

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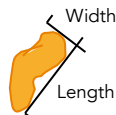
FFPE sample submission

Preferred method

1. Verify tissue is as large as a grain of rice (3mm²)

 (actual size)

2. Send whole block



Alternate method

1. Measure tissue (length x width) in mm
area = $\frac{\text{Length}}{\text{Width}} \times \text{Width} = \text{mm}^2$

2. If < 25mm², send whole block

3. If ≥ 25mm², send 4µm-5µm slides as below:

$$\begin{matrix} 1 & + & 1 & + & \text{---} & + & 4 & = & \text{---} \\ \text{H\&E} & & \text{NGS} & & \# \text{ of IHC*} & & \text{Reflex} & & \text{Slides needed} \end{matrix}$$

* MMR panel requires 4 slides for 4 IHCs

Paradigm Diagnostics
445 N 5th St., Suite 300
Phoenix, AZ 85004

About PCDx

PCDx is a comprehensive genomic profiling test designed to analyze solid tumor alterations to match the best therapies and clinical trials based on the latest clinical evidence in peer-reviewed literature.

Paradigm is able to accept most U.S. insurance plans, including Medicare. 43% of patients receiving therapy as directed by PCDx achieved a progression-free survival ratio of 1.3 compared to only 5% of patients treated by physician directed therapy¹.

¹Oncotarget, 7(35), 56491-56500.

Indications

PCDx is indicated when a patient has:

- a. a solid neoplasm; and
- b. recurrent, relapsed, refractory, metastatic or advanced (stage III/IV) cancer; and
- c. has not been tested by PCDx for the same cancer; and
- d. has decided to seek further treatment

Rejection criteria

A specimen will be rejected when it:

- a. contains less than 15% tumor cells after dissection; or
- b. is not of sufficient size as described above; or
- c. has been decalcified (exception: EDTA); or
- d. the specimen is not FFPE

Turnaround time

5 business days

Sensitivity

≥99%

Specificity

≥99%

Drug associations

~90

234 gene NGS panel

ABCB1	APC	B2M	CCNE1	CSF1R	EPCAM	FANCA	FGFR3	HNF1A	KRAS	MRE11A	NOTCH3	PIK3R1	RBM10	SMAD4	TSC1
ABCC1	APLN	BAP1	CD274	CTLA4	EPHA5	FANCC	FGFR4	HRAS	MAF	MSH2	NPM1	PLCB4	RECQL	SMARCA4	TSC2
ABCC2	AR	BARD1	CDA	CTNNB1	EPHA7	FANCD2	FLT3	HSD3B1	MAP2K1	MSH6	NRAS	PLCG1	RET	SMARCB1	TSHR
ABL1	ARAF	BCOR	CDC73	CYP19A1	ERBB2	FANCE	FLT4	IDH1	MAP2K2	MTHFR	NTRK1	PMS2	RHEB	SMO	TYMS
ADAMTS1	AREG	BNIP3	CDH1	CYP1A1	ERBB3	FANCF	FOXL2	IDH2	MAP3K1	MTOR	NTRK2	POLD1	RICTOR	SOC1	VEGFA
ADAMTS16	ARID1A	BRAF	CDK12	CYP2D6	ERBB4	FANGC	FUBP1	IGF1R	MAPK1	MUTYH	NTRK3	POLE	RIT1	SPOP	VHL
ADAMTS18	ARID1B	BRCA1	CDK4	CYP3A4	ERCC1	FANCM	GATA3	IKZF1	MAPK3	MYC	NTRK3	PPP2R1A	RNF43	STAG2	WT1
ADAMTS6	ARID2	BRCA2	CDK6	CYSLTR2	ERCC2	FAT1	GLI1	JAK1	MAPKAPK5	MYCN	PBRM1	PTCH1	ROS1	STAT3	XRCC1
ADAMTS9	ATM	BRIP1	CDKN2A	DCK	ERCC3	FBXW7	GNA11	JAK2	MDM2	MYOD1	PDCD1LG2	PTEN	RPTOR	STK11	YES1
ADAMTSL1	ATR	BTB	CHEK1	DDR2	ERRFI1	FCGR2A	GNAQ	JAK3	MDM4	NBN	PDGFRA	PTPN11	RRM1	SUFU	
AKT1	ATR	BUB1B	CHEK2	DICER1	ESR1	FGD4	GNAS	KDM5C	MED12	NF1	PDGFRB	RAD50	SDHB	TERT-p	
AKT2	AURKA	CBL	CHFR	DNMT3A	ESR2	FGF3	GSTP1	KDM6A	MEN1	NF2	PIK3CA	RAD51C	SDHC	TGFBR2	
AKT3	AURKB	CCND1	CHKA	EGFR	EWSR1	FGF4	GSTT1	KDR	MET	NFE2L2	PIK3CB	RAD51D	SETD2	TNFAIP3	
ALK	AXIN1	CCND2	CIC	EMSY	EZH2	FGFR1	HDAC2	KEAP1	MGMT	NOTCH1	PIK3CD	RAF1	SF3B1	TOP2A	
AMER1	AXL	CCND3	CREBBP	EP300	FAM175A	FGFR2	HGF	KIT	MLH1	NOTCH2	PIK3CG	RB1	SMAD2	TP53	

Genetic structures tested: single nucleotide variants (SNVs) and insertions/deletions up to 40bp in coding regions of genes listed above. UTRs and splice junctions when actionable (e.g., MET exon 14 skipping). Mutation burden (SNVs, insertions, deletions) based on ~1 megabase. Sensitivity and specificity above refer to SNVs, insertions and deletions. High-level amplifications will be reported for all genes when detected.

Limitations: Mutation calls may not be available from some regions due to pseudogenes or sequence context. Select IHCs may not be run if already performed within the last six months unless indicated in the notes section.

Reflex policy: Positive findings for ROS1 or TRKpan IHC will be reflexed to confirm presence of a fusion.