

Test Requisition Form

Please Fax to 866-444-0640

Questions? 866-662-6897 or oncotypemap@exactsciences.com

Patient information			
Name (Last, First, MI)			
DOB (MM/DD/YYYY)	Sex at birth <input type="checkbox"/> Unknown <input type="checkbox"/> Female or XX <input type="checkbox"/> Male or XY	Phone (primary)	
Street Address			
City	State	Postal code	Country (if not USA)
Does the Patient have any of the following: recurrent, relapsed, refractory, advanced (Stage III/IV) or metastatic cancer? <input type="checkbox"/> Yes <input type="checkbox"/> No If no you may be contacted			
Primary Tumor Site & Type			ICD-10 Code


Treating physician	
Physician Name / NPI #	Fax
Office/Practice/Institution	
Email	
Address	
Contact Phone	Office Contact Name
Contact Email(s)	

Pathology information			
Office/Practice/Institution		Specimen Information (for Pathology)	
Address		Specimen ID	Collection Date
Email		Format Submitted: <input type="checkbox"/> FFPE Block <input type="checkbox"/> Slides <input type="checkbox"/> Curls	
Phone	Fax	Anatomic Collection Site	Date Block Pulled from Archive

Testing Options		
<input type="checkbox"/> Pan-Cancer Tissue: NGS (257 genes incl. fusions, MSI ¹ , TMB) + IHC Panel Breast ² AR, PD-L1(SP142), PD-L1(22C3), TP Colorectal: HER2, PD-L1(22C3), TOP1, PTEN, TS NSCLC: PD-L1(22C3), ALK, PD-L1(SP142), PTEN, TS Other: See reverse		
<input type="checkbox"/> I understand and accept that HER2 equivocal by IHC will be reflexed for FISH testing in select tumor type.		
1. Will substitute MMR if not suitable for MSI. 2. ER, PR, HER2 results required for breast. Document previous results for ER/PR/HER2, otherwise HER2, ER, PR IHCs added to panel.	Individual IHCs <input type="checkbox"/> ALK <input type="checkbox"/> MET <input type="checkbox"/> PTEN <input type="checkbox"/> AR <input type="checkbox"/> MGMT <input type="checkbox"/> ROS1 <input type="checkbox"/> CAIX <input type="checkbox"/> MMR (4 IHC) <input type="checkbox"/> TOP1 <input type="checkbox"/> ER <input type="checkbox"/> PD1 <input type="checkbox"/> TP <input type="checkbox"/> hENT1 <input type="checkbox"/> PD-L1 (22C3) <input type="checkbox"/> TRKpan <input type="checkbox"/> HER2 <input type="checkbox"/> PD-L1 (SP142) <input type="checkbox"/> TS <input type="checkbox"/> IDO <input type="checkbox"/> PR <input type="checkbox"/> TUBB3	Individual Molecular <input type="checkbox"/> NGS (incl. fusions, MSI, TMB)

Submission checklist	
<ul style="list-style-type: none"> Signed/dated requisition (this form) Pathology report Demographics page Front/back of insurance card Clinical progress note 	Previous Results² ER <input type="checkbox"/> pos high <input type="checkbox"/> pos low <input type="checkbox"/> neg <input type="checkbox"/> n/a PR <input type="checkbox"/> pos <input type="checkbox"/> neg <input type="checkbox"/> n/a HER2 <input type="checkbox"/> pos <input type="checkbox"/> neg <input type="checkbox"/> equivocal <input type="checkbox"/> n/a HER2 Results From: <input type="checkbox"/> IHC <input type="checkbox"/> FISH
Notes or instructions:	

Billing information		
Bill to:		
<input type="checkbox"/> Private Insurance <input type="checkbox"/> Medicare <input type="checkbox"/> Medicaid <input type="checkbox"/> Patient <input type="checkbox"/> Bill Pathology Account Contracted Accounts Only		
<input type="checkbox"/> Other _____		
Primary Insurance	Member ID	Group #
Primary Policy Holder		DOB
Secondary Insurance	Member ID	Group #
Patient status <input type="checkbox"/> Office (Non-hospital) <input type="checkbox"/> Outpatient if Medicare <input type="checkbox"/> Inpatient (discharge date) _____		

Certificate of medical necessity, consent, test authorization, and physician signature		
By my signature below, I certify that: I am the treating physician; this testing is medically necessary for the patient and the results will be used for further medical management and treatment decisions for the patient; I have informed the patient about this testing and have received the patient's informed consent to proceed with the testing; and I have received the patient's consent for Exact Sciences to release test results for purposes of reimbursement from insurers. I acknowledge that the testing panel selected will be based on the most updated requisition and test description provided on the Exact Sciences website.		
 _____ Treating Physician Signature	_____ Printed Name	_____ / _____ / _____ Date (MM/DD/YYYY)

Turnaround time
3-5 business days

Drug associations
104 therapies and 48 combinations

257 gene NGS panel

ABCB1	APC	BMPRI1A	CDK4	DNMT3A	FANCC	GAS6	JAK3	MLH1	NTRK1	PTCH1	SETD2	TGFB2
ABCC1	APLNLR	BMPRI1B	CDK6	EGFR	FANCD2	GATA3	KDM5C	MPL	NTRK2	PTEN	SF3B1	TGFB3
ABCC2	AR	BNIP3	CDKN2A	EMSY	FANCE	GLI1	KDM6A	MRE11A	NTRK3	PTPN11	SMAD1	TGFBRI
ABL1	ARAF	BRAF	CHEK1	EP300	FANCF	GNAI1	KDR	MSH2	PALB2	RAD50	SMAD2	TGFBRI2
ACVR1	AREG	BRCA1	CHEK2	EPCAM	FANCG	GNAQ	KEAP1	MSH6	PBRM1	RAD51C	SMAD4	TNFAIP3
ACVR1B	ARID1A	BRCA2	CHFR	EPHA5	FANCM	GNAS	KIT	MTHFR	PDCD1LG2	RAD51D	SMAD5	TNK1
ACVR2A	ARID1B	BRIP1	CHKA	EPHA7	FAT1	GSTP1	KRAS	MTOR	PDGFRA	RAF1	SMAD9	TOP2A
ACVR2B	ARID2	BTK	CIC	ERBB2	FBXW7	HAMP	MAF	MUTYH	PDGFRB	RB1	SMARCA4	TP53
ACVRL1	ATM	BUB1B	CREBBP	ERBB3	FCGR2A	HDAC2	MAP2K1	MYC	PIK3CA	RBM10	SMARCB1	TSC1
ADAMTS1	ATR	CALR	CSF1R	ERBB4	FGD4	HGF	MAP2K2	MYCN	PIK3CB	RECQL	SMO	TSC2
ADAMTS16	ATRX	CBL	CTLA4	ERCC1	FGF3	HNFA	MAP3K1	MYOD1	PIK3CD	RET	SOCS1	TSHR
ADAMTS18	AURKA	CCND1	CTNNB1	ERCC2	FGF4	HRAS	MAPK1	NBN	PIK3CG	RHEB	SPOP	TYMS
ADAMTS6	AURKB	CCND2	CYP19A1	ERCC3	FGFR1	HSD3B1	MAPK3	NF1	PIK3R1	RICTOR	STAG2	VEGFA
ADAMTS9	AXIN1	CCND3	CYP1A1	ERRF1	FGFR2	IDH1	MAPKAPK5	NF2	PIM1	RIT1	STAT3	VHL
ADAMTSL1	AXL	CCNE1	CYP2D6	ESR1	FGFR3	IDH2	MDM2	NFE2L2	PLCB4	RNF43	STAT5A	WT1
AKT1	B2M	CD274	CYP3A4	ESR2	FGFR4	IGF1R	MDM4	NOTCH1	PLCG1	ROSI	STAT5B	XRCC1
AKT2	BAP1	CDA	CYSLTR2	EWSR1	FLT3	IKZF1	MED12	NOTCH2	PMS2	RPTOR	STK11	YES1
AKT3	BARD1	CDC73	DCK	EZH2	FLT4	IL6R	MEN1	NOTCH3	POLD1	RRM1	SUFU	
ALK	BCOR	CDH1	DDR2	FAM175A	FOXL2	JAK1	MET	NPM1	POLE	SDHB	TERT-p	
AMER1	BMP6	CDK12	DICER1	FANCA	FUBP1	JAK2	MGMT	NRAS	PPP2R1A	SDHC	TGFB1	

Genetic structures tested: single nucleotide variants (SNVs) and insertions/deletions in coding regions of genes listed above; UTRs and splice junctions when actionable (e.g., MET exon 14 skipping and EGFRV833); MSI; mutation burden (SNVs, insertions, deletions) based on -1 megabase; select fusions involving ALK, BRAF, FGFR1, FGFR2, FGFR3, MET, RET, ROS1, NTRK1, NTRK2, NTRK3 (ETV6); and copy number variants.

Turnaround time is based on when the sample is received. 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. HER2 equivocal by IHC will be reflexed for FISH testing in select tumor types. Reflex testing will exceed standard turn around time for results. MMR includes the following IHCs: MLH1, MSH2, MSH6, PMS2.

Other IHC panels

Anal Carcinoma: PD-L1(22C3), PD-1, TS, TUBB3
Appendix: HER2, PD-L1(22C3), TOPI, PTEN
Bladder: PD-L1(22C3), PD-L1(SP142), hENT1, TUBB3
Bone Cancer: TOPI, MGMT, CAIX, hENT1
CNS/brain cancers: MGMT, CAIX, TUBB3, TOPI
Cervical: PD-L1(22C3), CAIX, hENT1, TOPI
Gastric/Esophageal: HER2, PD-L1(22C3), PTEN, TS
GIST: PD-L1(22C3), MET
Head and Neck: PD-L1(22C3), CAIX, TUBB3, PTEN
Head and Neck Salivary Gland: HER2, AR, CAIX, PTEN
Hepatobiliary/Cholangiocarcinoma: hENT1, HER2, TP, PD-L1(22C3)

Hepatobiliary/Gallbladder: hENT1, HER2, PD-L1(22C3), TOPI
Hepatobiliary/Hepatocellular: hENT1, PD-L1(22C3), CAIX, MET
Kidney: PD-L1(22C3), MET, CAIX, hENT1
Melanoma: PD-L1(22C3), MGMT, PTEN, TUBB3
Mesothelioma: PD-L1(22C3), TS, hENT1, TUBB3
Neuroendocrine: PD-L1(22C3), MGMT, PTEN, TP
Non-melanoma: TS, PD-L1(22C3), CAIX, TOPI
Ovarian: ER, HER2, TOPI, TUBB3
Pancreatic: hENT1, PTEN, TP, TOPI
Penile Cancer: PD-L1(22C3), TP, CAIX, TUBB3
Prostate: AR, PTEN, TUBB3, PD-L1(22C3)

Sarcoma: CAIX, TUBB3, TOPI, MGMT
SLC: PD-L1(22C3), TOPI, MGMT
Small Bowel: TOPI, CAIX, TUBB3, hENT1
Testicular Cancer: PD-L1(22C3), TUBB3, hENT1
Thyroid: PD-L1(22C3), ALK, TUBB3, CAIX
Thymoma/Thymic Carcinoma: PD-L1(22C3), TUBB3, hENT1, TS
Uterine: ER, HER2, MGMT, TUBB3
Uveal Melanoma: PD-L1(22C3), MGMT, TUBB3
Vulvar Cancer: PD-L1(22C3), CAIX, TUBB3, hENT1
Other solid tumors: PD-L1(22C3), HER2, TOPI, PTEN, TS

Indications

Pan-Cancer Tissue is indicated when a patient has:

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

Acceptance criteria

A specimen will be rejected for NGS when:

- a. it contains <15% tumor cells after dissection; or
- b. it is not of sufficient size as described below; or
- c. it is not FFPE; or
- d. It is a decalcified specimen for NGS testing (exception: EDTA) and a decalcified specimen may be contraindicated in some IHCs.

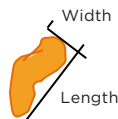
Testing Priority

NGS is run first, then IHCs are run in the order listed until complete or the block is exhausted. Specify in notes if a different priority is required. MSI may require higher % tumor. MMR will be substituted if MSI isn't possible.

FFPE Sample Requirements

- Estimate tissue surface area as width x length
- Send block/slides with largest tissue area to maximize success

Exact Sciences
445 N 5th St., Suite 300
Phoenix, AZ 85004



Preferred

Surface area ≥ 10mm²
Tumor content ≥ 20%

Send whole block or 8-10 slides 4-5um thick

Acceptable

Surface area: 3mm² →
Tumor content: 15%

Send whole block

Verify tissue as large as grain of rice. Actual size:

Exact Sciences Oncotype MAP™ Pan-Cancer Tissue Requisition Form Instructions

Instructions for completing the Oncotype MAP™ Pan-Cancer Tissue Requisition Form are highlighted below. These instructions provide a general overview, for questions please contact Customer Service at 866-662-6897 or oncotypemap@exactsciences.com. If required information is not provided, the test may be delayed and you may be contacted by Customer Service. To order online, please visit: online.genomichealth.com

If your patient's disease applies to ANY of these scenarios, please select this box. If a patient with Medicare insurance does not have recurrent, relapsed, refractory, metastatic, or advanced (stage III/IV) criteria, an ABN* will be required for NGS testing since Medicare would not consider the test medically necessary. Please select this box if ANY of these apply to your patient's diagnosis.

The primary ICD-10 code to support the medical necessity for the test ordered should be provided. Please fill out only one code arising from the primary tumor.

An ABN* may be required. See ABN guidance* for requirements.

Select the checkbox for the Pan-Cancer Tissue IHC Panel(s) for your order. if you would like to run both the NGS and IHC testing for this patient.

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Questions? 866-662-6897 or oncotypemap@exactsciences.com



Patient information Name (Last, First, MI) DOB (MM/DD/YYYY) Sex at birth <input type="checkbox"/> Unknown <input type="checkbox"/> Phone (primary) <input type="checkbox"/> Female or XX <input type="checkbox"/> Male or XY Street Address City State Postal code Country (if not USA) Does the Patient have any of the following: recurrent, relapsed, refractory, advanced (Stage III/IV) or metastatic cancer? <input type="checkbox"/> Yes <input type="checkbox"/> No If no you may be contacted Primary Tumor Site & Type ICD-10 Code		Treating physician Physician Name / NPI # Fax Office/Practice/Institution Email Address Contact Phone Office Contact Name Contact Email(s)	
Pathology information Office/Practice/Institution Address Email Phone Fax		Specimen Information (for Pathology) Specimen ID Collection Date Format Submitted: <input type="checkbox"/> FPPE Block <input type="checkbox"/> Slides <input type="checkbox"/> Curls Anatomic Collection Site Date Block Pulled from Archive	
Testing Options <input type="checkbox"/> Pan-Cancer Tissue: NGS (257 genes incl. fusions, MSI, TMB) + IHC Panel Breast ² AR, PD-L1(SPI42), PD-L1(22C3), TP Colorectal: HER2, PD-L1(22C3), TOP1, PTEN, TS NSCLC: PD-L1(22C3), ALK, PD-L1(SPI42), PTEN, TS Other: See reverse <input type="checkbox"/> I understand and accept that HER2 equivocal by IHC will be reflexed for FISH testing in select tumor type.			
Submission checklist • Signed/dated requisition (this form) • Pathology report • Demographics page • Front/back of insurance card • Clinical progress note Notes or instructions:		Individual IHCs <input type="checkbox"/> ALK <input type="checkbox"/> MET <input type="checkbox"/> PTEN <input type="checkbox"/> AR <input type="checkbox"/> MGMT <input type="checkbox"/> ROS1 <input type="checkbox"/> CAIX <input type="checkbox"/> MMR (4 IHC) <input type="checkbox"/> TOP1 <input type="checkbox"/> ER <input type="checkbox"/> PDI <input type="checkbox"/> TP <input type="checkbox"/> HENT1 <input type="checkbox"/> PD-L1 (22C3) <input type="checkbox"/> TRKpan <input type="checkbox"/> HER2 <input type="checkbox"/> PD-L1 (SPI42) <input type="checkbox"/> TS <input type="checkbox"/> IDO <input type="checkbox"/> PR <input type="checkbox"/> TUBB3	
Previous Results² ER <input type="checkbox"/> pos high <input type="checkbox"/> pos low <input type="checkbox"/> neg <input type="checkbox"/> n/a PR <input type="checkbox"/> pos <input type="checkbox"/> neg <input type="checkbox"/> n/a HER2 <input type="checkbox"/> pos <input type="checkbox"/> neg <input type="checkbox"/> equivocal <input type="checkbox"/> n/a HER2 Results From: <input type="checkbox"/> IHC <input type="checkbox"/> FISH		Individual Molecular <input type="checkbox"/> NGS (incl. fusions, MSI, TMB)	
Billing information Bill to: <input type="checkbox"/> Private Insurance <input type="checkbox"/> Medicare <input type="checkbox"/> Medicaid <input type="checkbox"/> Patient <input type="checkbox"/> Bill Pathology Account Contracted Accounts Only <input type="checkbox"/> Other Primary Insurance Member ID Group # Primary Policy Holder DOB Secondary Insurance Member ID Group # Patient status <input type="checkbox"/> Office (Non-hospital) <input type="checkbox"/> Outpatient If Medicare <input type="checkbox"/> Inpatient (discharge date)			
Certificate of medical necessity, consent, test authorization, and physician signature By my signature below, I certify that I am the treating physician; this testing is medically necessary for the patient and the results will be used for further medical management and treatment decisions for the patient; I have informed the patient about this testing and have received the patient's informed consent to proceed with the testing; and I have received the patient's consent for Exact Sciences to release test results for purposes of reimbursement from insurers. I acknowledge that the testing panel selected will be based on the most updated requisition and test description provided on the Exact Sciences website.			
Treating Physician Signature		Printed Name / / Date (MM/DD/YYYY)	

The specimen collection date is required to determine if an order is impacted by the Medicare 14-Day Rule and should be billed to the relevant hospital. If it is not provided for a patient with Medicare insurance, you will be contacted for this information.

This date is required to accurately determine the Date of Service according to the CMS Laboratory Date of Service policy.

Patient Hospital Status is required to ensure compliance with the Medicare 14-day rule. If it is not provided for a patient with Medicare insurance, you will be contacted for this information.

If submission checklist items are not sent with your original order, you may be contacted for this information if required by the patient's insurance.

*ABN: Advanced beneficiary notice
 Please refer to Oncotype MAP™ Pan-Cancer Tissue Test ABN Information (part number EXS50107). Available from your sales representative