

PHENOPATH USE ONLY

SPECIMEN INFORMATION

Facility specimen collected at		
Collection Date	Collection Time	
Multiple specimens submitted: <input type="checkbox"/> Test Separately <input type="checkbox"/> Select Best <input type="checkbox"/> Combine		
Pathology Report: <input type="checkbox"/> Included <input type="checkbox"/> Not Available		
Specimen ID	Sublabel	Specimen Source

REQUESTING ENTITY NAME & ADDRESS

Block(s), submitted stained slides and report will be returned to the Ordering Physician at the address/FAX listed below (unless otherwise requested):	
Name (Client ID)	
Add1	
Add2	
City, ST Zip	
Phone:	FAX#:
Ordering Physician Name	NPI#
Ordering provider signature, credentials & date requested (required by certain payers)	

PROGNOSTIC MARKER STUDIES FIXATION (ASCO/CAP Requirement)

Fixative: <input type="checkbox"/> 10% NBF (Neutral Buffered Formalin) <input type="checkbox"/> Other
Fixation duration (please circle): <6 hours 6-72 hours >72 hours Unknown
Collection Time: _____ AM/PM Time Placed in Fixative: _____ AM/PM

PATIENT INFORMATION

Name (Last, First, MI)	
DOB	<input type="checkbox"/> Male <input type="checkbox"/> Female
Medical Record #	Pt #
Address	
Phone	
<input type="checkbox"/> Inpatient <input type="checkbox"/> Outpatient <input type="checkbox"/> Non-Hospital Patient	

CONTACT INFORMATION

Person completing form	
Date	Phone

Many payers (including Medicare and Medicaid) have medical necessity requirements. You should only order those tests which are medically necessary for the diagnosis and treatment of the patient.

BILLING INFO (If complete and accurate patient billing information is not provided, PhenoPath may bill the requesting entity)

BILL: <input type="checkbox"/> Insurance <input type="checkbox"/> Patient <input type="checkbox"/> Requesting entity	
PO#	<input type="checkbox"/> PO not required ICD-10
*If 3 rd -party billing is requested, a copy of face sheet and front/back of patient's ins/Medicare card must be attached, or client will be billed. Direct-bill regulations prohibit PhenoPath from billing a 3 rd -party entity	
† If requesting entity has been selected, ENTIRE billing demographics MUST be documented below	
If pre-authorization is required but is not obtained, PhenoPath will bill the requesting entity	
Attn:	Entity Name
Department	Address
City, ST Zip	
Billing Contact Phone #:	FAX#:

TREATING PHYSICIAN (for billing purposes, write/type in the name of the treating physician)

<input type="checkbox"/> Mail/fax copy of report to treating physician; IF ALL INFO BELOW IS NOT COMPLETED, report will NOT be faxed or mailed	
Physician Name:	
Facility Name:	
Mailing Address	
Phone #:	FAX#:

G=Global (w/ interp)/ TC=Tech only (w/o interp)

IMMUNOTHERAPY BIOMARKERS

G	TC		G	TC	
<input type="checkbox"/>	N/A	PD-L1 (22C3) IHC (Keytruda)	<input type="checkbox"/>	N/A	PD-L1 (28-8) IHC (Opdivo)
<input type="checkbox"/>	<input type="checkbox"/>	PD-L1 (E1L3N) IHC (generic)	<input type="checkbox"/>	N/A	PD-L1 (SP142) IHC (Tecentriq)
<input type="checkbox"/>	N/A	PD-L1 SP263 (FDA-approved)			
<input type="checkbox"/>	<input type="checkbox"/>	MLH1 IHC	<input type="checkbox"/>	<input type="checkbox"/>	MSH2 IHC
<input type="checkbox"/>	<input type="checkbox"/>	MMR IHC panel (MLH1, MSH2, MSH6, and PMS2)	<input type="checkbox"/>	<input type="checkbox"/>	PMS2 IHC
<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	MSH6 IHC
<input type="checkbox"/>	N/A	MSI PCR (requires separate tumor and normal tissue specimens (peripheral blood is acceptable for the normal specimen))			

BREAST CARCINOMA

G	TC		G	TC	
<input type="checkbox"/>	<input type="checkbox"/>	ER IHC	<input type="checkbox"/>	<input type="checkbox"/>	PR IHC
<input type="checkbox"/>	<input type="checkbox"/>	HER2 IHC	<input type="checkbox"/>	<input type="checkbox"/>	p53 IHC
<input type="checkbox"/>	<input type="checkbox"/>	Basal-like breast (nestin, INPP4B) IHC			
<input type="checkbox"/>	N/A	ER IHC (if negative, run PR IHC)			
<input type="checkbox"/>	N/A	HER2 IHC (if equivocal, run HER2 FISH)			
<input type="checkbox"/>	N/A	HER2 FISH (include your HER2 IHC slide)			
<input type="checkbox"/>	N/A	HER2 FISH (run HER2 IHC if required by guidelines)			
<input type="checkbox"/>	N/A	ER, PR, HER2 IHC (if HER2 is equivocal, run HER2 by FISH)			

AMYLOID TYPE ANALYSIS

<input type="checkbox"/>	<input type="checkbox"/>	Congo Red	<input type="checkbox"/>	<input type="checkbox"/>	Amyloid A IHC
<input type="checkbox"/>	<input type="checkbox"/>	Amyloid P IHC	<input type="checkbox"/>	<input type="checkbox"/>	Kappa IHC
<input type="checkbox"/>	<input type="checkbox"/>	Lambda IHC	<input type="checkbox"/>	<input type="checkbox"/>	Transthyretin IHC
<input type="checkbox"/>	N/A	Amyloid type analysis panel (congo red, amyloid A, amyloid P, kappa, lambda, and transthyretin)			
<input type="checkbox"/>	N/A	Amyloid type analysis panel w/o congo red (Amyloid A, amyloid P, kappa, lambda, and transthyretin) (you must submit your congo red)			

HEAD & NECK CARCINOMA

<input type="checkbox"/>	<input type="checkbox"/>	p16 IHC
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LUNG CARCINOMA

G	TC		G	TC	
<input type="checkbox"/>	N/A	PD-L1 (22C3) IHC (Keytruda)	<input type="checkbox"/>	N/A	PD-L1 (28-8) IHC (Opdivo)
<input type="checkbox"/>	N/A	PD-L1 (SP142) IHC (Tecentriq)	<input type="checkbox"/>	N/A	PD-L1 (E1L3N) IHC (generic)
<input type="checkbox"/>	N/A	ALK (for lung ca) IHC (if + or equivocal, run ALK by FISH)	<input type="checkbox"/>	<input type="checkbox"/>	ROS1 IHC
<input type="checkbox"/>	N/A	ROS1 IHC (if + or equivocal, run ROS1 by FISH)			
<input type="checkbox"/>	N/A	ALK (for lung ca) IHC	<input type="checkbox"/>	N/A	ROS1 by FISH
<input type="checkbox"/>	N/A	ALK by FISH	<input type="checkbox"/>	N/A	EGFR by PCR
<input type="checkbox"/>	N/A	MET by FISH	<input type="checkbox"/>	N/A	BRAF V600 by PCR
<input type="checkbox"/>	N/A	RET by FISH			
<input type="checkbox"/>	N/A	EGFR PCR (if negative, run ALK FISH)			
<input type="checkbox"/>	N/A	EGFR PCR (if negative, run ALK FISH, and if ALK is negative, run ROS1 FISH)			
<input type="checkbox"/>	N/A	EGFR PCR (if negative, run ALK FISH; if ALK is negative, run ROS1 FISH; and if ROS1 is negative, run MET FISH and RET FISH)			
<input type="checkbox"/>	N/A	EGFR PCR (if negative, run ALK FISH; and if ALK is negative, run ROS1 FISH, MET FISH and RET FISH)			
<input type="checkbox"/>	N/A	PD-L1 (22C3) IHC, EGFR PCR, ALK FISH, and ROS1 FISH (if EGFR, ALK and ROS1 are negative, run MET FISH and RET FISH)			

GASTRIC/GASTROESOPHAGEAL NEOPLASMS

G	TC		G	TC	
<input type="checkbox"/>	N/A	PD-L1 (22C3) IHC (Keytruda)	<input type="checkbox"/>	<input type="checkbox"/>	PD-L1 (E1L3N) IHC (generic)
<input type="checkbox"/>	<input type="checkbox"/>	HER2 by IHC			
<input type="checkbox"/>	N/A	HER2 IHC (if equivocal, run HER2 FISH)			
<input type="checkbox"/>	N/A	HER2 FISH (include your IHC slide)			
<input type="checkbox"/>	N/A	HER2 FISH (perform HER2 IHC if required by guidelines)			
<input type="checkbox"/>	N/A	KIT (c-KIT) mutation analysis* (GIST)			
<input type="checkbox"/>	N/A	PDGFRa mutation analysis* (GIST)			
<input type="checkbox"/>	<input type="checkbox"/>	IDH1 by IHC	<input type="checkbox"/>	<input type="checkbox"/>	ATRX by IHC
<input type="checkbox"/>	N/A	1p/19q by FISH			
<input type="checkbox"/>	N/A	MGMT promoter methylation analysis *			

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LYNCH SYNDROME & COLON CARCINOMA

G	TC		G	TC	
<input type="checkbox"/>	<input type="checkbox"/>	MLH1 IHC	<input type="checkbox"/>	<input type="checkbox"/>	MSH2 IHC
<input type="checkbox"/>	<input type="checkbox"/>	MSH6 IHC	<input type="checkbox"/>	<input type="checkbox"/>	PMS2 IHC
<input type="checkbox"/>	<input type="checkbox"/>	HER2 IHC	<input type="checkbox"/>	N/A	HER2 FISH
<input type="checkbox"/>	N/A	HER2 IHC (if equivocal, run HER2 FISH)			
<input type="checkbox"/>	<input type="checkbox"/>	MMR IHC panel (MLH1, MSH2, MSH6, PMS2)			
<input type="checkbox"/>	N/A	MMR IHC panel (colon) (if there is loss of MLH1 and PMS2, run BRAF V600 by PCR)			
<input type="checkbox"/>	N/A	MMR IHC panel (endometrial) (if there is loss of MLH1 and PMS2, run MLH1 promoter methylation analysis *)			
<input type="checkbox"/>	N/A	MMR IHC panel (if there is loss of MLH1 and PMS2, run BRAF V600 by PCR, and if BRAF is negative, run MLH1 promoter methylation analysis *)			
<input type="checkbox"/>	N/A	MSI by PCR (requires separate tumor and normal tissue specimens (peripheral blood is acceptable for the normal specimen))			
<input type="checkbox"/>	N/A	KRAS Exon 2 (FDA-approved) by PCR			
<input type="checkbox"/>	N/A	Extended KRAS/NRAS (KRAS exons 3, 4 and NRAS exons 2,3,4)			
<input type="checkbox"/>	N/A	KRAS Exon 2 (FDA-approved) by PCR (if negative, run Extended KRAS/NRAS)			
<input type="checkbox"/>	<input type="checkbox"/>	BRAF V600 by PCR			
<input type="checkbox"/>	N/A	BRAF V600 (if - order MLH1 promoter methylation*)			

MELANOMA

<input type="checkbox"/>	N/A	PD-L1 (22C3) IHC (Keytruda)	<input type="checkbox"/>	N/A	PD-L1 (28-8) IHC (Opdivo)
<input type="checkbox"/>	<input type="checkbox"/>	PD-L1 (E1L3N) IHC (generic)			
<input type="checkbox"/>	N/A	BRAF V600 (in melanoma) (FDA-approved) by PCR			
<input type="checkbox"/>	N/A	NRAS mutation analysis *			
<input type="checkbox"/>	N/A	KIT (c-kit) mutation analysis*			

MOLAR PREGNANCY

<input type="checkbox"/>	<input type="checkbox"/>	p57 by IHC	<input type="checkbox"/>	<input type="checkbox"/>	Ki-67 (MIB-1) by IHC
<input type="checkbox"/>	N/A	CEP17 by FISH			
<input type="checkbox"/>	N/A	p57 by IHC, Ki-67 (MIB-1) by IHC, and CEP17 by FISH			
<input type="checkbox"/>	N/A	p57 by IHC, Ki-67 (MIB-1) by IHC, and CEP17 by FISH with consult (diagnosis)			

NOTES

* Send-out testing not performed by PhenoPath; by ordering the test, you authorize the send-out and agree to accept financial responsibility.

Reflex and additional testing performed at an additional charge. NOTES: Most tests listed in a panel may be ordered individually (use "directed tests" section or write-in request if not listed); tests for other disease states may also be available; full consult available; visit our website or call 1.866.927.4366 for more information.

Send: <input type="checkbox"/> Reqs (List req #)	<input type="checkbox"/> Transport Kits	<input type="checkbox"/> TC Transport Kits	<input type="checkbox"/> RPMI	<input type="checkbox"/> Michels	<input type="checkbox"/> Other	Date Needed By:
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By submitting a specimen with this requisition form, you agree:

- 1) The information provided on this form and accompanying paperwork is complete and accurate.
- 2) If the information is not accurate, and PhenoPath cannot obtain reimbursement for services that have been requested and provided, Client agrees to accept financial responsibility.
- 3) If the test order is ambiguous, PhenoPath may contact client to determine intent. Testing may be delayed.
- 4) Requests for testing PhenoPath does NOT perform (for current test menu, consult PhenoPath's website – www.phenopath.com or contact Client Services at 1.206.374.9000, or Toll-free at 1.888.92.PHENO (1.888.927.4366):
 - a) PhenoPath may forward specimens to an alternate facility for testing it does not perform, upon authorization by Client.
 - b) PhenoPath will manage return of applicable specimen to Client.
 - c) By signing the authorization form, Client agrees to pay for authorized services that are not paid for by a third party. PhenoPath can only bill for professional services provided by PhenoPath.

ICD-10 – All providers, laboratories, institutions, hospitals, and other providers ordering laboratory testing to be performed by PhenoPath Laboratories must provide all clinically relevant ICD-10-CM diagnosis codes for all testing submitted.

Direct Bill Law – Washington is a “direct-bill” state for anatomic pathology services (<http://apps.leg.wa.gov/rcw/default.aspx?cite=48.43.081>, RCW 48.43.081). This means that for specimens originating in the State of Washington, PhenoPath can only send a bill to the entity that ordered the services (or to the patient or their insurance).

MEDICARE COVERAGE DETERMINATIONS – PhenoPath is a Medicare participating provider, and is subject to the local coverage determinations (LCD) of the Medicare Administrative Contractor (MAC) for Jurisdiction F, Noridian Healthcare Solutions, Contractor No. 02402. Additional information can be obtained online at: <https://www.noridianmedicare.com/partb/coverage/active.html>.

MEDICARE MEDICAL NECESSITY REQUIREMENTS – When ordering laboratory tests that are billed to Medicare/Medicaid or other federally funded programs, the following requirements may apply:

- 1) Only tests that are medically necessary for the diagnosis or treatment of the patient should be ordered. Medicare does not pay for screening tests, except for certain specifically approved procedures, and may not pay for non-FDA-approved tests or tests considered experimental.
- 2) If there is reason to believe that Medicare will not pay for a test, the patient should be informed, and asked to sign an Advanced Beneficiary Notice (ABN) to indicate whether he/she accepts responsibility for the cost of the test if Medicare denies payment.
- 3) The ordering physician must provide all clinically relevant ICD-10 diagnosis codes, not a narrative description, in order to support the medical necessity of each test ordered. Providing ICD-10 codes on the Requisition will avoid unnecessary phone calls to physician and client offices as well as delays in service to patients to obtain medical necessity documentation. PhenoPath may contact Client to obtain diagnosis information for reasons including, but not limited to the following:
 - A diagnosis code is not provided.
 - The provided diagnosis appears inconsistent with the patient's demographic, the patient's medical condition or the testing services being ordered.
 - The provided diagnosis does not meet the coverage criteria as supporting medical necessity for testing services covered by a Medicare LCD.
- 4) Organ- or disease-oriented panels should be billed to Medicare only when every component of the panel is medically necessary. The OIG takes the position that a physician who orders medically unnecessary tests for which Medicare reimbursement is claimed may be subject to civil penalties. PhenoPath- and client-customized panels should be billed to Medicare only when every component of the customized panel is medically necessary. PhenoPath offers groups of tests based on accepted clinical practice.

Advanced Beneficiary Notice (“ABN”) – An ABN, Form CMS-R-131, is a standardized notice you must issue to a Medicare beneficiary before providing certain Medicare Part B (outpatient) or Part A (limited to hospice, home health agencies [HHAs], and Religious Nonmedical Healthcare Institutions only) items or services. You must issue the ABN when:

- You believe Medicare may not pay for an item or service;
- Medicare usually covers the item or service; and
- Medicare may not consider the item or service medically reasonable and necessary for this patient in this particular instance. You should only provide ABNs to beneficiaries enrolled in original (fee-for-service) Medicare. ABNs allow beneficiaries to make informed decisions about whether to get services and accept financial responsibility for those services if Medicare does not pay. The ABN serves as proof the beneficiary knew prior to getting the service that Medicare might not pay. If you do not issue a valid ABN to the beneficiary when Medicare requires it, you cannot bill the beneficiary for the service, and you may be financially liable if Medicare doesn't pay. You may also use the ABN as an optional (voluntary) notice to alert beneficiaries of their financial liability prior to providing care that Medicare never covers. ABN issuance is not required to bill a beneficiary for an item or service that is not a Medicare benefit and never covered.
- If you order a test that does not meet Medicare's medical necessity guidelines, it is important that you complete an ABN and have it signed by the patient at the time of service. This will allow you and PhenoPath to bill the patient for the services provided if Medicare does not reimburse us for the test(s) and if the patient has accepted the financial responsibility. Medicare defines medical necessity as services that are: reasonable and necessary, for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member, and not excluded under another provision of the Medicare Program. All services reported to the Medicare Program by healthcare professionals must demonstrate medical necessity through the use of International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) diagnostic coding carried to the highest level of specificity for the date of service.

Physician Clinical Consultant: PhenoPath's pathologists are available to discuss appropriate testing and test ordering with ordering physicians.