PhenoPath

A Quest Diagnostics Company

Toll-free: 1.888.92.PHENO
P 1.206.374.9000
F 1.206.374.9009
www.phenopath.com

THIS SECTION FOR PHENOPATH USE ONLY

CANCER TYPE

PHENOPATH USE ONLY

SPECIMEN INFORMATION

Facility specimen collected at

Collection Date	Collection Time

Multiple specimens submitted: ☐ **Test Separately** ☐ **Select Best** ☐ **Combine**

Pathology Report: ☐ **Included** ☐ **Not Available**

Specimen ID	Sublabel	Specimen Source

PROGNOSTIC MARKER STUDIES FIXATION *(ASCO/CAP Requirement)*

Fixative: ☐ 10% NBF (Neutral Buffered Formalin) ☐ 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	☐ Male	☐ Female

Medical Record #	Pt #

Address

Phone

☐ Inpatient ☐ Outpatient ☐ Non-Hospital Patient

CONTACT INFORMATION

Person completing form

Date	Phone

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)

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: ☐ Insurance ☐ Patient ☐ Requesting entity

PO# ☐ PO not required	ICD-10

*If 3rd-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 3rd-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)

☐ 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	
☐	N/A	PD-L1 (22C3) IHC (Keytruda)	☐	N/A	PD-L1 (28-8) IHC (Opdivo)
☐	☐	PD-L1 (E1L3N) IHC (generic)	☐	N/A	PD-L1 (SP142) IHC (Tecentriq)
☐	N/A	PD-L1 SP263 (FDA-approved)			
☐	☐	MLH1 IHC	☐	☐	MSH2 IHC
☐	☐	MMR IHC panel (MLH1, MSH2, MSH6, and PMS2)	☐	☐	PMS2 IHC
			☐	☐	MSH6 IHC
☐	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	
☐	☐	ER IHC	☐	☐	PR IHC
☐	☐	HER2 IHC	☐	☐	p53 IHC
☐	☐	Basal-like breast (nestin, INPP4B) IHC			
☐	N/A	ER IHC (if negative, run PR IHC)			
☐	N/A	HER2 IHC (if equivocal, run HER2 FISH)			
☐	N/A	HER2 FISH (include your HER2 IHC slide)			
☐	N/A	HER2 FISH (run HER2 IHC if required by guidelines)			
☐	N/A	ER, PR, HER2 IHC (if HER2 is equivocal, run HER2 by FISH)			

AMYLOID TYPE ANALYSIS

☐	☐	Congo Red	☐	☐	Amyloid A IHC
☐	☐	Amyloid P IHC	☐	☐	Kappa IHC
☐	☐	Lambda IHC	☐	☐	Transthyretin IHC
☐	N/A	Amyloid type analysis panel (congo red, amyloid A, amyloid P, kappa, lambda, and transthyretin)			
☐	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

☐	☐	p16 IHC

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LUNG CARCINOMA

G	TC		G	TC	
☐	N/A	PD-L1 (22C3) IHC (Keytruda)	☐	N/A	PD-L1 (28-8) IHC (Opdivo)
☐	N/A	PD-L1 (SP142) IHC (Tecentriq)	☐	N/A	PD-L1 (E1L3N) IHC (generic)
☐	N/A	ALK (for lung ca) IHC (if + or equivocal, run ALK by FISH)	☐	☐	ROS1 IHC
☐	N/A	ROS1 IHC (if + or equivocal, run ROS1 by FISH)			
☐	N/A	ALK (for lung ca) IHC	☐	N/A	ROS1 by FISH
☐	N/A	ALK by FISH	☐	N/A	EGFR by PCR
☐	N/A	MET by FISH	☐	N/A	BRAF V600 by PCR
☐	N/A	RET by FISH			
☐	N/A	EGFR PCR (if negative, run ALK FISH)			
☐	N/A	EGFR PCR (if negative, run ALK FISH, and if ALK is negative, run ROS1 FISH)			
☐	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)			
☐	N/A	EGFR PCR (if negative, run ALK FISH; and if ALK is negative, run ROS1 FISH, MET FISH and RET FISH)			
☐	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	
☐	N/A	PD-L1 (22C3) IHC (Keytruda)	☐	☐	PD-L1 (E1L3N) IHC (generic)
☐	☐	HER2 by IHC			
☐	N/A	HER2 IHC (if equivocal, run HER2 FISH)			
☐	N/A	HER2 FISH (include your IHC slide)			
☐	N/A	HER2 FISH (perform HER2 IHC if required by guidelines)			
☐	N/A	KIT (c-KIT) mutation analysis* (GIST)			
☐	N/A	PDGFRa mutation analysis* (GIST)			

MALIGNANT GLIOMAS

☐	☐	IDH1 by IHC	☐	☐	ATRX by IHC
☐	N/A	1p/19q by FISH			
☐	N/A	MGMT promoter methylation analysis *			

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LYNCH SYNDROME & COLON CARCINOMA

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

MELANOMA

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

MOLAR PREGNANCY

☐	☐	p57 by IHC	☐	☐	Ki-67 (MIB-1) by IHC
☐	N/A	CEP17 by FISH			
☐	N/A	p57 by IHC, Ki-67 (MIB-1) by IHC, and CEP17 by FISH			

NOTES

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

Send: ☐ **Reqs (List req #)** _____ ☐ **Transport Kits** ☐ **TC Transport Kits** ☐ **RPMI** ☐ **Michels** ☐ **Other** _____ **Date Needed By:** _____

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.