

**THIS SECTION FOR PHENOPATH USE ONLY**

**MOLECULAR**

**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 \_\_\_\_\_

**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# \_\_\_\_\_

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.

**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

**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, State Zip \_\_\_\_\_

Billing Contact Phone #: \_\_\_\_\_ FAX#: \_\_\_\_\_

**PATIENT INFORMATION**

Name (Last, First, MI) \_\_\_\_\_

DOB \_\_\_\_\_  Male  Female SSN # \_\_\_\_\_

Medical Record # \_\_\_\_\_ Pt # \_\_\_\_\_

Address \_\_\_\_\_

Phone \_\_\_\_\_

Inpatient  Outpatient  Non-Hospital Patient

**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#: \_\_\_\_\_

**CONTACT INFORMATION**

Person completing form \_\_\_\_\_

Date \_\_\_\_\_ Phone \_\_\_\_\_

**MOLECULAR: Hematologic Malignancies (go to www.phenopath.com for specimen requirements)**

<p><b>Gene Rearrangement Studies</b></p> <p><input type="checkbox"/> IgH <input type="checkbox"/> TCR-gamma</p> <p><input type="checkbox"/> Ig-Kappa <input type="checkbox"/> TCR-beta</p> <p><input type="checkbox"/> IgH &amp; Ig-Kappa <input type="checkbox"/> TCR-gamma &amp; TCR-beta</p> <p><input type="checkbox"/> IgH (if negative, perform Ig-Kappa) <input type="checkbox"/> TCR-gamma (if negative, perform TCR-beta)</p>	<p><b>Other Molecular Studies</b></p> <p><input type="checkbox"/> BCR-ABL1 major &amp; minor <input type="checkbox"/> BCR-ABL1 major (p210) only <input type="checkbox"/> BCR-ABL1 minor (p190) only</p> <p><input type="checkbox"/> BCR-ABL1 major &amp; minor (if both are NOT detected, perform JAK2 V617F)</p> <p><input type="checkbox"/> Calreticulin Exon 9 (CALR) <input type="checkbox"/> BRAF V600 (for hairy cell leukemia)</p> <p><input type="checkbox"/> JAK2 V617F <input type="checkbox"/> MYD88 L265P</p> <p><input type="checkbox"/> JAK2 V617F (if negative, perform JAK2 Exon 12*) (PV) <input type="checkbox"/> IgVH mutation analysis (CLL)*</p> <p><input type="checkbox"/> JAK2 V617F (if negative, perform CALR, and if CALR is negative, perform MPL) (ET/PMF)</p> <p><input type="checkbox"/> JAK2 Exon 12* <input type="checkbox"/> MPL (W515)</p> <p><input type="checkbox"/> LeukoVantage - MDS* <input type="checkbox"/> LeukoVantage - AML* <input type="checkbox"/> LeukoVantage - MPN*</p>
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**MOLECULAR: Solid Tumors - FISH studies can be ordered individually on the FISH requisition form**

BRAF V600  BRAF V600 (in melanoma) (FDA-approved)

Watson Genomics from Quest, Core NGS\*  Oncomine Dx Target Test NGS

EGFR (FDA-approved)  EGFR (FDA-approved) and ALK FISH  EGFR (FDA-approved), and ALK & ROS1 FISH

EGFR (if negative, perform ALK FISH)

EGFR (if negative, perform ALK FISH; and if ALK is negative, perform ROS1 FISH)

EGFR (if negative, perform ALK FISH; if ALK is negative, perform ROS1 FISH; and if ROS1 is negative, perform MET and RET FISH)

EGFR (if negative, perform ALK FISH; and if ALK is negative, perform ROS1, RET and MET FISH)

KRAS Exon 2 (FDA-approved)  KRAS Exon 2 (FDA-approved) (if negative, perform Extended KRAS/NRAS)

Extended KRAS/NRAS (KRAS exons 3, 4 and NRAS exons 2, 3, 4)

MSI (requires separate tumor and normal tissue specimens (peripheral blood is acceptable for the normal specimen))

MGMT methylation\*  MLH1 promoter methylation\*

**PD-L1 IHC Tests**

PD-L1 (22C3) (Keytruda)

PD-L1 (28-8) (Opdivo)

PD-L1 (SP142) (Tecentriq)

PD-L1 (E1L3N) (generic)

**NOTES**

Reflux 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](http://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.

# PhenoPath

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