PhenoPath
Diagnoses you can count on®
Toll-free: (888) 92-PHENO
P (206) 374-9000
F (206) 374-9009
www.phenopath.com

THIS SECTION FOR PHENOPATH USE ONLY

EGFR PLASMA

PHENOPATH USE ONLY

SPECIMEN INFORMATION - ALL information in this section MUST be completed before testing is performed

Facility specimen collected at _____

NOTE: Plasma must be separated within 4 hours of blood collection

Specimen ID: _____

Blood collection: Date _____ Time _____

Plasma separation: Date _____ Time _____

Collection Tube Type: ❑ K2-EDTA/plasma separator tube
❑ Other _____

Reason for testing:
☐ Inadequate biopsy
☐ Unable to obtain biopsy
☐ Monitoring / resistance mutation testing

PATIENT INFORMATION

Name (Last, First, MI) _____

DOB _____ ❑ Male ❑ Female SSN # _____

Medical Record # _____ Pt # _____

Address _____

Phone _____

❑ Inpatient ❑ Outpatient ❑ Non-Hospital Patient

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)
Department
Address
City, ST ZIP
Phone: / FAX:

Ordering Physician Name _____ NPI# _____

Medicare and other third party payors require services be medically necessary for coverage and generally do not cover routine screening tests.

BILLING INFO (Complete & accurate information must be provided, including billing instruction, or requesting entity will be billed)

BILL: ❑ Insurance* ❑ Patient ❑ Requesting entity†

ICD-10 _____

PO# _____ Referral/Auth # _____

* 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#: _____

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: _____ Entity Name: _____

Mailing Address _____ Phone _____ Fax _____

CONTACT INFORMATION

Person completing form _____ Date _____ Phone _____

DIRECTED TESTING (check to order)

☐ cobas® plasma (cfDNA) EGFR mutation testing

NOTES

COLLECTION REQUIREMENTS

- Venipuncture into K2-EDTA/plasma separator tube (ideally collect two to three 5mL tubes; minimum of one 5mL tube needed)
- Within 4 hours of blood collection, separate plasma by centrifugation
- Transfer plasma into transport tube
- Immediately ship to PhenoPath frozen, on dry ice

NOTE: PhenoPath does not provide shipping labels to ship plasma specimens

SAMPLE REQUIREMENTS

- **Minimum** of 2mL plasma (collected as instructed above)
- **Recommend** 4-6mL plasma for testing

NOTE: ~ 5mL of whole blood needed to obtain ~ 2mL of plasma

REJECTION CRITERIA

- Plasma separated > 4 hours after venipuncture
- Samples **NOT** received frozen on dry ice

If sample is rejected, client will be contacted, and testing will not be performed.

METHODOLOGY / TEST DESCRIPTION

The Roche cobas® cfDNA Sample Preparation Kit is used to isolate circulating cell-free DNA (cfDNA) from plasma samples, which is used as the sample template for the cobas® EGFR Mutation Test v2.

The cobas® EGFR Mutation Test is a DNA based real-time PCR assay which detects mutations in exons 18, 19, 20 and 21 of the epidermal growth factor receptor (EGFR) gene, including: the **T790M mutation** in exon 20, G719X (G719A, G719C, and G719S) mutations in exon 18, deletions and complex mutations in exon 19, S768I and insertion mutations in exon 20, and the L858R and L861Q mutations in exon 21.

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 866-927-4366 for more information.

* Sendout testing not performed by PhenoPath

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 a service does not have an established Medicare allowable, PhenoPath will bill the Client.
4) If the test order is ambiguous, PhenoPath may contact client to determine intent. Testing may be delayed.
5) Requests for testing PhenoPath does NOT perform (for current test menu, consult PhenoPath's website – www.phenopath.com or contact Client Services at *206.374.9000*, or Toll-free at *888.92.PHENO* (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 PhenoPath can only send a bill to the entity that ordered the services (or to the patient or their insurance). We cannot bill a 3rd party.

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.

PRE-AUTHORIZATION – If pre-authorization is required but is not obtained, and the insurance company denies payment due to lack of pre-authorization, the requesting entity will be billed.

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 Advance 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 health care 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.
- If the testing does not meet Medicare medical necessity guidelines, the patient does not sign an ABN, and Medicare fails to reimburse for the test(s) ordered, PhenoPath will bill the referring lab/physician for the services provided.

PhenoPath's billing practices have been developed to ensure compliance with federally mandated rules. Direct questions about invoices to our Medical Billing department at 1-866-927-4366 or 206-374-1480. Fax inquiries to 206-774-3412. The department is generally staffed Monday to Friday from 6 am to 4:30 pm Pacific time.

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

PhenoPath
Diagnoses you can count on®