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PhenoPath
Diagnoses you can count on®

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E

Plasma cfDNA EGFR Mutation Testing

THIS SECTION FOR PHENOPATH USE ONLY

cobas® EGFR PLASMA

SPECIMEN INFORMATION

Institution where specimen collected:_____

_____

Blood collection*: Date _____ Time_____

Plasma separation*: Date

_____ Time _____

Collection Tube Type*: ☐K2-EDTA/plasma separator tube

☐Other_____

*REQUIRED

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

Reason for testing:

☐Inadequate biopsy

☐Unable to obtain biopsy

SAMPLE REQUIREMENTS

- **Minimum** of 2mL plasma (using collection instructions below)
- **Recommend** 4-6 mL plasma for testing

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

COLLECTION INSTRUCTIONS

- Venipuncture into K2-EDTA/plasma separator tube (ideally collect two to three 5 mL tubes; minimum of one 5 mL 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

REJECTION CRITERIA

If sample does not meet acceptability criteria, client will be contacted and testing will not be performed.

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

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.

DIRECTED TESTING (list desired test below)

☑ cobas® plasma (cfDNA) EGFR mutation testing

NOTES

REQUESTING INSTITUTION NAME & ADDRESS

Material and report will be returned to the address provided below:

Phone _____ FAX _____

Ordering Pathologist/Physician

Name _____ NPI # _____

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

PATIENT INFORMATION

Name (Last, First, MI) _____

SSN # _____ DOB _____ ☐Male ☐Female

☐Inpatient ☐Outpatient ☐Non-Hospital Patient

Address _____

_____ Phone _____

Medical Record # _____ Pt # _____

TREATING PHYSICIAN

_____

Name NPI #

☐ Mail/Fax add'l copy of report to treating physician
Information REQUIRED, if not complete report will **NOT** be faxed/mailed

Phone _____ Fax _____

Institution _____

Address _____

City, State Zip _____

BILLING INFO (Complete and accurate information must be provided, including billing instructions, or Client will be billed)

BILL: ☐ Insurance* ☐ Medicare ☐ Medicaid (WA DSHS only)

☐ Requesting Institution† ☐ Patient

PO# _____ ICD-10 # _____

Referral/Authorization # _____

*If 3rd party billing is requested, a copy of the face sheet and front/back of patient's insurance/Medicare card MUST be attached

†If bill requesting institution has been selected, ENTIRE billing address MUST be included

Institution _____

Address _____

City, State Zip _____

CONTACT INFO

Person completing form _____

Date _____ Phone _____

Send: REQS: ☐Heme ☐Molecular ☐IHC ☐Derm ☐Solid Tumor ☐PhenoBoxes ☐Flow Media ☐IF Media ☐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) 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 ICD-10-CM diagnosis codes for all testing submitted for dates of service October 1, 2015 and greater.
Links: https://www.cms.gov/Medicare/Coding/ICD10/index.html?redirect=/ICD10 and http://www.cdc.gov/nchs/icd/icd10cm.htm#icd2014

Direct Bill Law – Washington is a "direct-bill" state for anatomic pathology services (RCW 48.43.081, http://apps.leg.wa.gov/rcw/default.aspx?cite=48.43.081). This means that PhenoPath can only send a bill to the entity who 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.

SELECTED LOCAL COVERAGE DETERMINATIONS (LCD)

LCD Title	LCD ID No.	Original Effective Date
Cytogenetic Studies	L24295	12/01/2006
Flow Cytometry	L35208	06/16/2015
Genetic Testing	L24308	12/01/2006
Genetic Testing for BCR-ABL Negative Myeloproliferative Disease	L36186	04/19/2016
MolDx: Breast Cancer Genetic Assay	L35500	06/22/2015
Non-Covered Services	L24473	11/01/2007
Special Histochemical Stains and Immunohistochemical Stains	L36353	10/15/2015

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) Diagnosis information is requested from ordering physicians in order to support the medical necessity of each test ordered. ICD-10 codes are required on the test requisition for dates of service October 1, 2015 and greater (ICD-9 codes are required for dates of service prior to October 1, 2015). Narrative descriptions may be acceptable. PhenoPath will contact Client to obtain diagnosis information for reasons including, but not limited to the following:

   - A diagnosis code or narrative description is not provided.
   - The provided diagnosis narrative description appears inconsistent with the patient's demographic, the patient's medical condition, or the testing services being ordered.
   - The provided diagnosis or narrative description 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 may 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.

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