

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#
Ordering provider signature, credentials & date requested (required by certain payers)

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

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#:

PATIENT INFORMATION

Name (Last, First, MI)
DOB Male Female
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

SPECIAL INSTRUCTIONS

CLINICAL HISTORY

FLOW CYTOMETRY (diagnosis under consideration)

Flow cytometry analysis based on clinical history and to rule out:
 Lymphoproliferative disorder Myeloid neoplasm MRD for Myeloma
 Plasma cell neoplasm Acute leukemia MRD for B-ALL
 PNH (FLAER) Other _____ MRD for T-ALL
 MRD for AML
 MRD for _____
 Perform FISH studies if indicated based on flow cytometry findings
 Perform _____ if _____
 Studies to be determined by PhenoPath pathologists
 Perform molecular studies if indicated based on flow cytometry findings
 Perform _____ if _____
 Studies to be determined by PhenoPath pathologists

MOLECULAR: Hematologic malignancies

AML Panel*: FLT3* NPM1* CEBPA* IDH1/IDH2*
 BCR-ABL1 major & minor BCR-ABL1 major (p210) only BCR-ABL1 minor (p190 only)
 JAK2 V617F
If JAK2 V617F is negative, order:
 JAK2 Exon 12 JAK2 exon 12-13 (72 hr specimen stability)
 CALR If CALR is negative, order MPL
 JAK2 exon 12 JAK2 exon 12-13 (72 hr specimen stability)
 CALR MPL
 CSF3R*
 MYD88 L265P MYD88 L265P (if negative, order CXCR4*)
 BRAF V600 (for hairy cell leukemia)
 IgVH mutation analysis (CLL)* NOTCH1* TP53*
 CLL/SLL profile NGS (Med Fusion)*: Includes BIRC3, BTK, MYD88, NOTCH1, PLCG2, SF3B1, TP53 molecular studies (1016113)
 CLL/SLL profile + IgVH mutation analysis (1017055)
 LeukoVantage - MDS* LeukoVantage - AML* LeukoVantage - MPN*
 LeukoVantage-General Myeloid* PML-RARA RT-PCR
Gene Rearrangement Studies
 IgH Ig-Kappa IgH & Ig-Kappa IgH (if negative, perform Ig-Kappa)
 TCR-gamma TCR-beta TCR-gamma & TCR-beta TCR-gamma (if negative, perform TCR-beta)

CYTOGENETICS

Chromosome analysis

FISH PANELS **Available on paraffin

ALL*: Probes vary by vendor; please contact PhenoPath Client Services for details
 AML: t(15;17) PML/RARA** CBFB inv16 Brk t(8;21) RUNX1/RUNX1T1
 MLL (11q23) Brk 7/del 7q CEP8 (trisomy) EGR1 (5q31/5p15.5)
 APL: t(15;17) PML/RARA** RARA Brk**
 CML: t(9;22) BCR/ABL**
 MDS: EGR1 (5q31/5p15.5) 7/del 7q Deletion 20q12 CEP8 (trisomy)
 Eosinophilia: PDGFRA-FIP1L1 PDGFRB Brk FGFR Brk

CLL/SLL: 17p13.1_P53 11q22.3_ATM 13q14.3_D13S319 13q34_LAMP
 CEP12 (trisomy) IGH Brk** t(11;14) CCND1/IGH**
 MALT1 Panel: MALT1 Brk**
Not available on fresh If MALT1 is +, run t(11;18) MALT/BIRC3
 Aggressive B-NHL: MYC Brk** t(8;14) MYC/IGH t(14;18) IGH/BCL2** BCL6 Brk**
 Myeloma (in the below-listed order of priority):
 IGH 14q32 Rea 17p13.1_P53 1q21+1p21 MYC Brk** 13q14.3_D13S319 13q34_LAMP
 t(11;14) CCND1/IGH** t(4;14) GFGR3/IGH** t(14;16) IGH/MAF** t(14;20) IGH/MAFB** CC9,CEP5,CC3
 CD138 enrichment needed*
*If the % of abnormal plasma cells is < 20% by flow cytometry or morphology, enrichment is needed; check box

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: _____

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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.