labcorp | Oncology

Client Services
TN:(800) 874-8532 fax: (615) 370-8074
AZ:(800) 710-1800 fax: (800) 481-4151
CT:(800) 447-5816 fax: (212) 698-9532

PROGNOSTIC/THERAPEUTIC PATHOLOGY

oncology.labcorp.com

Highlighted fields are REQUIRED

CLIENT INFORMATION

ORDERING PHYSICIAN	NPI #
TREATING PHYSICIAN	NPI #
PHYSICIAN/AUTHORIZED SIGNATURE	

Client#

Client Name

Address

Phone Number Fax Number

PATIENT INFORMATION

Name (LAST, FIRST, MIDDLE):

Date of Birth: Sex: ☐ Male ☐ Female

Address:

City, State, Zip:

Phone Number:

Med. Rec. # / Patient #:

BILLING INFORMATION (attach face sheet and copy of insurance card – both sides)

Bill: ☐ My Account ☐ Insurance ☐ Medicare ☐ Medicaid ☐ Patient ☐ Workers Comp
Patient Hospital Status: ☐ In-Patient ☐ Out-Patient ☐ Non-Patient
Insurance Information: ☐ See attached Authorization # _____

PRIMARY BILLING PARTY	SECONDARY BILLING PARTY
INSURANCE CARRIER*	INSURANCE CARRIER*
ID #	ID #
GROUP #	GROUP #
INSURANCE ADDRESS	INSURANCE ADDRESS
NAME OF INSURED PERSON	NAME OF INSURED PERSON
RELATIONSHIP TO PATIENT	RELATIONSHIP TO PATIENT
EMPLOYER NAME	EMPLOYER NAME

*IF MEDICAID STATE | PHYSICIAN'S PROVIDER # | WORKERS COMP ☐ Yes ☐ No

CLINICAL/SPECIMEN INFORMATION

Collection Date: Time: Fixative: ☐ 10% Neutral Buffered Formalin

Send Date: ☐ Other:

Required for Breast Cancer: Time to Fixation: Hours Fixed:

Body Site/Descriptor: ☐ See previous case history

Specimen ID# (as it appears on the specimen):

Narrative Diagnosis/Clinical Data (Please provide pathology report):

☐ Paraffin Block(s): #_____ ☐ Choose best block (default) ☐ Slides: #_____ ☐ Smears: # _____
☐ Perform tests on all blocks ☐ Plasma: ☐ Other:_____

BLOCK PROCUREMENT

Block Location: Do you have possession of the block? ☐ Yes ☐ No
If No, indicate the location (below) and fax completed requisition to your lab location (see fax #s at top of requisition).

Facility Name:

Attention/Dept:

Address:

Phone Number: Fax Number:

CLINICAL INDICATION (attach clinical history and pathology reports)

All diagnoses should be provided by the ordering physician or an authorized designee.
Diagnosis/Signs/Symptoms in ICD-CM format in effect at Date of Service (Highest Specificity Required)

ICD-CM | ICD-CM | ICD-CM

When ordering tests for which Medicare or Medicaid reimbursements will be sought, physicians should order only those tests that are medically necessary for the diagnosis or treatment of the patient.

ⓘLynch Syndrome Comprehensive Tumor Evaluation includes MLH1/MSH2/MSH6/PMS2 (IHC), and MSI (PCR). If MLH1 is deficient, reflex to BRAF mutation analysis. If negative, reflex to MLH1^ promoter methylation. If ordering for endometrial cancer, BRAF mutation analysis will not be performed.

TESTING REQUESTED

IMMUNOHISTOCHEMISTRY LEVEL OF SERVICE – MUST SELECT ONE

☐ IHC stain with Manual Interpretation
☐ IHC stain with Quantitative Image Analysis (Global; Breast only)
☐ IHC stain - Technical Component only (slides)
☐ IHC stain with Virtual Image - Technical Component only

BREAST CANCER

HER2 requires formalin-fixed tissue; equivocal IHC results (2+) will be reflexed to FISH

Panels:
☐ ER♦, PR♦
☐ ER♦, PR♦, HER2 (IHC)♦
☐ ER♦, PR♦, HER2 (IHC)♦, Ki-67♦
☐ ER♦, PR♦, HER2 (FISH)
☐ ER♦, PR♦, HER2 (FISH), Ki-67♦

Reflex Options:
☐ HER2 (FISH); if Group 2,3 or 4, reflex to IHC
☐ ER, PR, HER2 IHC (w/2+ reflex to HER2 FISH), if all negative, reflex to PD-L1 22C3 (KEYTRUDA®)IHC ¥
☐ ER, PR, HER2 (FISH), if all 3 negative, reflex to PD-L1 22C3 (KEYTRUDA®)IHC ¥

Individual Tests:
☐ ER♦
☐ PR♦
☐ HER2 (IHC)♦
☐ Ki-67♦
☐ HER2 (FISH)
☐ p53♦
☐ DNA ploidy
☐ E-Cadherin
☐ PD-L1 22C3 (KEYTRUDA®) IHC ¥ for TNBC
☐ PIK3CA mutation analysis, IVD
☐ Tamoxifen CYP2D6 Genotype

☐ **Prosigna® Breast Cancer Prognostic Gene Signature Assay**
☐ **ER, PR, HER2 (IHC); if ER/PR+ HER2-, reflex to Prosigna®**
REQUIRED FOR PROSIGNA®: Gross Tumor Size (must select one) ☐ ≤ 2 cm ☐ > 2 cm
Nodal Status (must select one) ☐ Negative ☐ 1-3 nodes

COLORECTAL CANCER

Panels:
☐ Comprehensive CRC Predictive Panel (Extended KRAS/NRAS, BRAF, MSI)
☐ Extended RAS/RAF Pathway Mutuation Panel (KRAS, NRAS, BRAF)
☐ Extended RAS Pathway Mutation Panel (KRAS, NRAS)

Panels for Lynch Syndrome:
☐ Lynch Syndrome Comprehensive Tumor Evaluationⓘ
☐ MLH1/MSH2/MSH6/PMS2 (MMR IHC)
☐ Reflex to MSI (PCR) if any IHC marker listed above is not expressed
☐ Reflex to BRAF if MLH1 is not expressed (Colorectal cancer only)
☐ MSI (PCR); if unstable, reflex to MLH1/MSH2/MSH6/PMS2 (MMR IHC)

Individual Tests:
☐ KRAS extended mutation (exons 2, 3, 4)★
☐ KRAS mutation, IVD (codons 12,13)
☐ NRAS extended mutation (exons 2, 3, 4)★
☐ BRAF mutation
☐ PMS2 (IHC)
☐ MLH1 (IHC)
☐ MSI (PCR)
☐ MSH2 (IHC)
☐ EGFR (FISH)
☐ MSH6 (IHC)
☐ UGT1A1

MSI by PCR: To note, tumor **and** normal tissue/peripheral blood required for MSI (PCR)
☐ If insufficient normal tissue submitted, perform MMR by IHC

NON-SMALL CELL LUNG CANCER

Panels:
☐ Comprehensive NSCLC Predictive Panel ([EGFR, KRAS, BRAF mutation analysis], [ALK, ROS1, RET by FISH], PD-L1 KEYTRUDA® by IHC¥)

Reflex Options:
☐ EGFR mutation; if result wild-type, reflex to: ☐ KRAS ☐ ALK (FISH) ☐ ROS1 ☐ RET
☐ EGFR mutation and ALK; if results wild-type/negative, reflex to: ☐ ROS1 ☐ RET ☐ KRAS

Individual Tests:
☐ EGFR mutation analysis
☐ KRAS mutation analysis
☐ BRAF mutation analysis
☐ ALK (FISH)
☐ ROS1 (FISH)
☐ RET (FISH)
☐ cMET (FISH)
☐ EGFR (FISH)
☐ ALK (D5F3) (IHC)
☐ EGFR mutation test, IVD (cobas®v2)
☐ KRAS mutation test, IVD (codons 12,13)

IMMUNOTHERAPY

Provide Pathology Report

Mismatch repair deficient tumors (any solid tumor)
☐ MMR IHC (MLH1/MSH2/MSH6/PMS2) ☐ MSI

PD-L1 (IHC) (Tumor types listed per FDA-approved kit package insert)

PD-L1 22C3 (KEYTRUDA®) - Global
☐ NSCLC#
☐ Cervical
☐ Esophogeal (Squamous cell only)
☐ SCC of the head and neck
☐ Triple-negative breast cancer (TNBC)
☐ PD-L1 KEYTRUDA Tech Only (88360-TC)

PD-L1 28-8 (OPDIVO®) - Global
☐ NSCLC
☐ SCC of the head and neck
☐ Urothelial carcinoma
☐ PD-L1 OPDIVO Tech Only (88360-TC)

PD-L1 SP142 (TECENTRIQ®)- Global
☐ NSCLC♦
☐ Urothelial carcinoma

PD-L1 SP263 (TECENTRIQ®)- Global
☐ NSCLC^
☐ PD-L1 SP142 TECENTRIQ Tech Only (88360-TC)
☐ PD-L1 SP263 TECENTRIQ Tech Only (88360-TC)

GASTRIC CANCER

Equivocal HER2 IHC results (2+) will be reflexed to FISH

☐ HER2 (FISH) & HER2 (IHC) ☐ HER2 (IHC) ☐ HER2 (FISH)

TESTS FOR OTHER CANCERS

Melanoma: ☐ BRAF mutation analysis (V600E/K) ☐ BRAF mutation analysis, IVD (THxID®) ☐ LAG-3 by IHC ¥
Ovarian: ☐ FOLR1 by IHC
GIST: ☐ cKIT mutation analysis ☐ PDGFRA mutation analysis
Glioblastoma: ☐ 1p19q deletions (FISH) ☐ MGMT methylation ☐ IDH1/IDH2 mutation analysis ☐ TERT promoter mutation assay
Thyroid: ☐ BRAF mutation analysis
Urothelial: ☐ FGFR mutation analysis, IVD

Additional tests: (Please visit www.oncology.labcorp.com to see a complete list of our testing services)

*Peripheral blood only ^Investigational use only ♦Antibodies can be available by quantitative image analysis
#This test can also be used for LIBTAYO® eligibility ¥ Global Only
♦PD-L1 SP142 CDx indication for late stage IV/metastatic NSCLC
^PD-L1 SP263 CDx indication for early stage II-IIIA NSCLC

Determining Necessity of Advance Beneficiary Notice of Non-coverage (ABN) Completion*

1. **Diagnose.** Determine your patient's diagnosis.
2. **Document.** Write the diagnosis code(s) on the front of this requisition.
3. **Verify.** Determine if the laboratory test(s) ordered for the patient is subject to the Local Coverage Determination or National Coverage Determination. This information can be located in the policies published by your Medicare Administrative Contractor (MAC), CMS, or www.Labcorp.com/MedicareMedicalNecessity.
4. **Review.** If the diagnosis code for your patient **does not** meet the medical necessity requirements set forth by Medicare or the test is being performed more frequently than Medicare allows, an ABN should be completed.

*An ABN should be completed for all tests that are considered investigational (experimental or for research use) by Medicare.

How to Complete an Advance Beneficiary Notice of Non-coverage (ABN)

Medicare is very specific in requiring that all of the information included on the ABN must be completed. Additionally, Labcorp requests that the specimen number or bar code label be included on the form. To be valid, an ABN must:

1. Be executed on the CMS approved ABN form (CMS-R-131).
2. Identify the Medicare Part B Beneficiary, using the name as it appears on the patient's red, white, and blue Medicare card.
3. Indicate the test(s)/procedure(s) which may be denied within the relevant reason column.
4. Include an estimated cost for the test(s)/procedures(s) subject to the ABN.
5. Have "Option 1", "Option 2", or "Option 3" designated by the beneficiary.
6. Be signed **and** dated by the beneficiary or his/her representative **prior to** the service being rendered.

Patient, client, and billing information is requested for timely processing of this case. Medicare and other third party payors require that services be medically necessary for coverage, and generally do not cover routine screening tests.

Refer to Determining Necessity of ABN Completion on reverse.

Symbols Legend

@ = Subject to Medicare medical necessity guidelines

^ = Medicare deems investigational. Medicare does not pay for services it deems investigational.

★Codons included in Colorectal Cancer Mutation Testing:

KRAS/NRAS

- Exon 2 Codons 12 and 13
- Exon 3 Codons 59 and 61
- Exon 4 Codons 117 and 146

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