

For general inquiries:
Ph: 800-366-7230
Fax: 919-361-7296
Email: AskCMBPOncology@labcorp.com
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Client #:
Client name:
Client address:
Phone #
Fax#

| | | | | | | | | | |
|---|------------------|---|----------------------------|---|--|--|------------------------------|-----|--------------------------------------|
| Patient's Legal Name (Last, First, MI) | | Sex | Date of Birth MO DAY YR | | Collection Time AM <input type="checkbox"/> Yes PM <input type="checkbox"/> No | Fasting <input type="checkbox"/> Yes <input type="checkbox"/> No | Collection Date MO DAY YR | | Urine hrs/vol hrs _____ vol _____ |
| NPI | Physician's ID # | Patient's ID # | | Hospital Patient Status: <input type="checkbox"/> In-Patient <input type="checkbox"/> Out-Patient <input type="checkbox"/> Non-Patient | | | | | |
| Physician's Name (Last,First) | | Physician/Authorized Signature X _____ | | Patient's Address | | | Phone | | |
| Diagnosis/Signs/Symptoms in ICD-CM format in effect at Date of Service Highest Specificity REQUIRED | | | | City | | State | | ZIP | |
| BILLING INFORMATION 03 Account Bill | | | | Name of Policy Holder (if different from patient) | | | | | |
| | | | | Address of Policy Holder | | | APT # | | |
| | | | | City | | State | | ZIP | |
| I hereby authorize the release of medical information related to the service described herein and authorize payment directly to Labcorp. I agree to assume responsibility for payment of charges for laboratory services that are not covered by my healthcare insurer. | | | | | | | | | |
| | | | | X Patient's Signature | | | Date | | |

Early Experience Program (EEP)

- For a limited period, Labcorp will perform the testing at no charge for eligible patients and will not bill or seek reimbursement from the patient's health insurance, or any other third-party payer. Likewise, during the EEP, physicians may not bill or seek reimbursement, of any kind, for the testing.
- To be eligible for the EEP, patients must have a diagnosis of stage III colon cancer. Testing should be initiated after curative intent treatment (after surgery and adjuvant chemotherapy). For more information on this test, please refer to the Labcorp Plasma Detect Genome MRD page (oncology.labcorp.com/cancer-care-team/solid-tumor/mrd/colon-cancer).

- Testing includes the Baseline test and three additional Monitoring tests within the 12-month period (a total of four tests per patient during the EEP).
- Following the conclusion of the EEP, Labcorp Plasma Detect Genome MRD will continue to be available to all patients, including those who were part of the EEP. Once the EEP period ends, Labcorp will commence billing for Labcorp Plasma Detect Genome MRD to the patient's health insurance provider or other responsible third-party payer.

Required relevant clinical history (select one):

- Patient has completed curative-intent surgery and will be undergoing adjuvant chemotherapy
- Patient is in disease remission (i.e., NO clinical or radiographic or biological evidence that tumor cells remain post treatment and subsequently the patient is no longer being subjected to therapeutic interventions for cancer)

Clinical and Specimen Information

Diagnosis/Indication

- Stage III colon cancer

Baseline test tissue

Surgery Date (required): _____

- Pathology report attached (required)
- Most recent progress/clinical note attached

Tissue acquisition to be managed by: (choose one)

- Labcorp and block procurement requested
- Clinic will coordinate shipping of sample

If Labcorp is procuring FFPE tissue:

For block procurement, submit the TRF with this section filled out to CMBPBlockProcure@labcorp.com. Include the term "SECURE EMAIL" in the subject line.

Facility name of specimen location:

Attention/Dept: _____

Phone Number: _____

Fax number: _____

If clinic is shipping FFPE tissue to Labcorp:

(FFPE, for complete specimen requirements see reverse):

Body site: _____

Collection date: _____

Send date: _____

Accession #/Block ID: _____

Blood specimens

- Whole blood

Date of collection: _____

TESTING REQUESTED

Labcorp Plasma Detect Genome MRD uses whole genome sequencing to detect circulating tumor DNA (ctDNA) in plasma in patients diagnosed with a solid tumor malignancy that are being monitored for recurrence or progression, potentially enabling proactive and timely intervention.

- Test code: 484442 – Baseline test (FFPE tissue and whole blood or whole blood only with FFPE tissue being shipped separately)** – The first timepoint as a baseline assessment of MRD after curative intent surgery.

Both FFPE tissue and whole blood are required to complete analysis. For optimal results, it is recommend that the baseline blood draw be performed 2-4 weeks after surgery. While this timing is based on current evidence, this can be adjusted based on a patient's individual clinical circumstances and clinicians' preference.

Use the Labcorp Plasma Detect Genome MRD specimen shipping kit only for collection and transportation.

- Test code: 484479 – Baseline test (FFPE tissue only)** – Use this test code when FFPE tissue is being sent without whole blood, and whole blood is being shipped separately.

- Test code: 484551 – Monitoring test (whole blood)** – For the purpose of surveillance monitoring after completion of definitive curative-intent therapy (surgery and adjuvant chemotherapy), orders can only be placed after the Baseline test has been completed.

Use the Labcorp Plasma Detect Genome MRD specimen shipping kit only for collection and transportation.

PHYSICIAN'S SIGNATURE AND CONSENT

My signature certifies that I have determined that the test(s) being ordered is medically necessary for the patient, certifies that the results of this test will inform the patient's ongoing treatment plan, and certifies that I am the patient's treating physician or that I have been authorized by the patient's treating physician to pursue genomic testing. I, or the patient's treating physician, have explained to the patient the nature and purpose of the test(s) to be performed and have obtained informed consent, to the extent required under applicable law, to permit Labcorp, or any laboratory with which Labcorp has contracted, to (a) perform the test(s) specified herein, (b) analyze and report on other genetic information generated during the testing process or conduct additional analyses of the patient's sample for future diagnostic or monitoring use, and (c) release the test results and related patient information to the patient's third-party payer as needed for reimbursement purposes. Further, unless specified, the patient consents for Labcorp to retain the test results and any residual tissues, blood, plasma, cells, and genetic material, including DNA and RNA, and information generated during the testing process, for an indefinite period for internal quality assurance/operations purposes, and remove information that directly identifies the patient from the test results, tissues, blood, plasma, cells, and genetic material, including DNA and RNA, information generated during the testing process, and use or disclose such information and materials for future unspecified research or other purposes.

Ordering Physician Signature _____

Printed Name _____ Date _____

- My patient would like to opt out of research use of any generated test results, tissues, cells, and genetic materials.

TEST COMBINATION / PANEL POLICY

Labcorp's policy is to provide physicians, in each instance, with the flexibility to choose appropriate tests to assure that the convenience of ordering test combinations/panels does not distance physicians who wish to order a test combination/profile from making deliberate decisions regarding which tests are truly medically necessary. All the tests offered in test combinations/panels may be ordered individually using the Labcorp® request form. Labcorp encourages clients to contact their local Labcorp representative or Labcorp location if the testing configurations shown here do not meet individual needs for any reason, or if some other combination of procedures is desired.

In an effort to keep our clients fully informed of the content, charges and coding of its test combinations/panels when billed to Medicare, we periodically send notices concerning customized test combinations/panels, as well as information regarding patient fees for all Labcorp services. We also welcome the opportunity to provide, on request, additional information in connection with our testing services and the manner in which they are billed to physicians, health care plans, and patients.

The CPT code(s) listed are in accordance with the current edition of Current Procedural Terminology, a publication of the American Medical Association. CPT codes are provided at our online test menu at www.Labcorp.com; however, correct coding often varies from one carrier to another. Consequently, the codes presented here are intended as general guidelines and should not be used without confirming with the appropriate payor that their use is appropriate in each case. All laboratory procedures will be billed to third-party carriers (including Medicare and Medicaid) at fees billed to patients and in accordance with the specific CPT coding required by the carrier. Microbiology CPT code(s) for additional procedures such as susceptibility testing, identification, serotyping, etc. will be billed in addition to the primary codes when appropriate. Labcorp will process the specimen for a microbiology test based on source.

Labcorp Plasma Detect Genome MRD

Labcorp Plasma Detect Genome MRD uses whole genome sequencing to detect circulating tumor DNA (ctDNA) in plasma in patients diagnosed with a solid tumor malignancy that are being monitored for recurrence or progression, potentially enabling proactive and timely intervention.

This test is not available to patients who are pregnant, have concurrent malignancies, received a blood transfusion within three months prior to a blood sample, or had an allogeneic bone marrow/stem cell transplant at any time.

Shipping

Please use the Labcorp Plasma Detect Genome MRD specimen shipping kit. Send to:
CMBP, Labcorp
1912 TW Alexander Drive
Durham, NC 27709
Attn: Specimen Management

Baseline Test Specimen Requirements:

Blood

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|----------------------|--|
| Blood | 10 mL whole blood per tube, collected in 2 Streck Cell-Free DNA tubes. |
| Storage and shipment | Specimens should be stored at room temperature and shipped overnight (using the provided MRD specimen kit) to the testing laboratory. Record the date and time of collection in the specimen information section. DO NOT refrigerate or freeze the specimen. |

Tissue

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|---------------------------------|--|
| Tissue Submission Guidelines | All blocks and slides must at a minimum be labeled with the pathology case number and block ID. Reports and other provided materials must be labeled with the pathology case number and at least two patient identifiers, such as name, medical record number or date of birth. INCLUDE THE PATHOLOGY REPORT. |
| Recommended Specimen Submission | The preferred specimen is at least one FFPE block. If a block cannot be provided, see slide requirements below. Specimens with very small amounts of tumor and/or less than requested number of slides will be accepted with the caveat that complete testing may not be possible. Specimens should be selected by a board-certified pathologist and should contain neoplastic and normal tissue, where indicated. It is recommended that unstained slides are cut using standard DNA/RNA precautions (change microtome blade, wipe stage, never re-use blade for more than one case and remove floaters in water bath between cases). |
| Slide Requirements | Block is preferred, or send 10 unbaked, positively charged, unstained slides cut at 5 µm. |

Monitoring Test Specimen Requirements:

Blood

| | |
|----------------------|--|
| Blood | 10 mL whole blood per tube, collected in 2 Streck Cell-Free DNA tubes. |
| Storage and shipment | Specimens should be stored at room temperature and shipped overnight (using the provided MRD specimen kit) to the CMBP testing laboratory. Record the date of collection in the specimen information section. DO NOT refrigerate or freeze the specimen. |