Foundation Medicine Requisition Form

Our Order Form Explained

Instructions for completing the Foundation Medicine Test Requisition Form for all tests are outlined below. These instructions provide a general overview, but please contact Client Services at 888.988.3639 or client.services@foundationmedicine.com for questions or further detail. Optional fields are indicated. All other fields are required. If required fields are not provided, the test may be delayed and you may be contacted by our Client Services Team. For more information or to order online, visit *www.foundationmedicine.com.*

1 Patient Information

Patient First Name, Last Name: Enter patient's full legal first name (no nicknames) and full legal last name (including any hyphenations).

2 Current Diagnosis/Patient History

Accurate diagnosis information helps inform health insurance coverage and supports faster turn-around-time by preventing follow-up from our Client Services, Billing and Pathology groups.

To prevent a delay in receiving results, include:

- Stage *OR* Disease Status, *AND*
- Cancer type, ICD Code(s)

Diagnosis: Current diagnosis. Choose cancer type or fill out "other". Provide any additional diagnosis information in the "Additional Details" section.

Attachments: Supplementary test results may assist our pathologists in their assessment of the case. Scan and include with submission. Utilizing online ordering will make this process easier.

3 Treating Physician Information

Treating Physician Name: Provide the full legal name of the physician here. This must match the signature line at the bottom of this form.

Foundation Medicine Account Number: If you do not know or do not have an account number, Foundation Medicine will create and/or enter it when we receive the order.

Additional Physician to be Copied: Physician indicated here will receive a copy of the report when it is available (if desired). To add more physicians, please use online ordering.

4 Test Selection

Select only one test (unless supplementing with IHC testing). For information on what test is right for your patient, refer to our website or contact Client Services.

Portfolio Reflex Option:
If the "Portfolio Reflex" checkbox is selected, we will proceed with the initial NGS test selected and if the specimen does not meet the criteria for successful testing, we will automatically reflex to the other test detailed below and procure a new specimen.

The failed test is not billed, and the successful test will be billed according to our standard practices. Please see https://www.foundationmedicine.com/genomic-testing/order for more information.

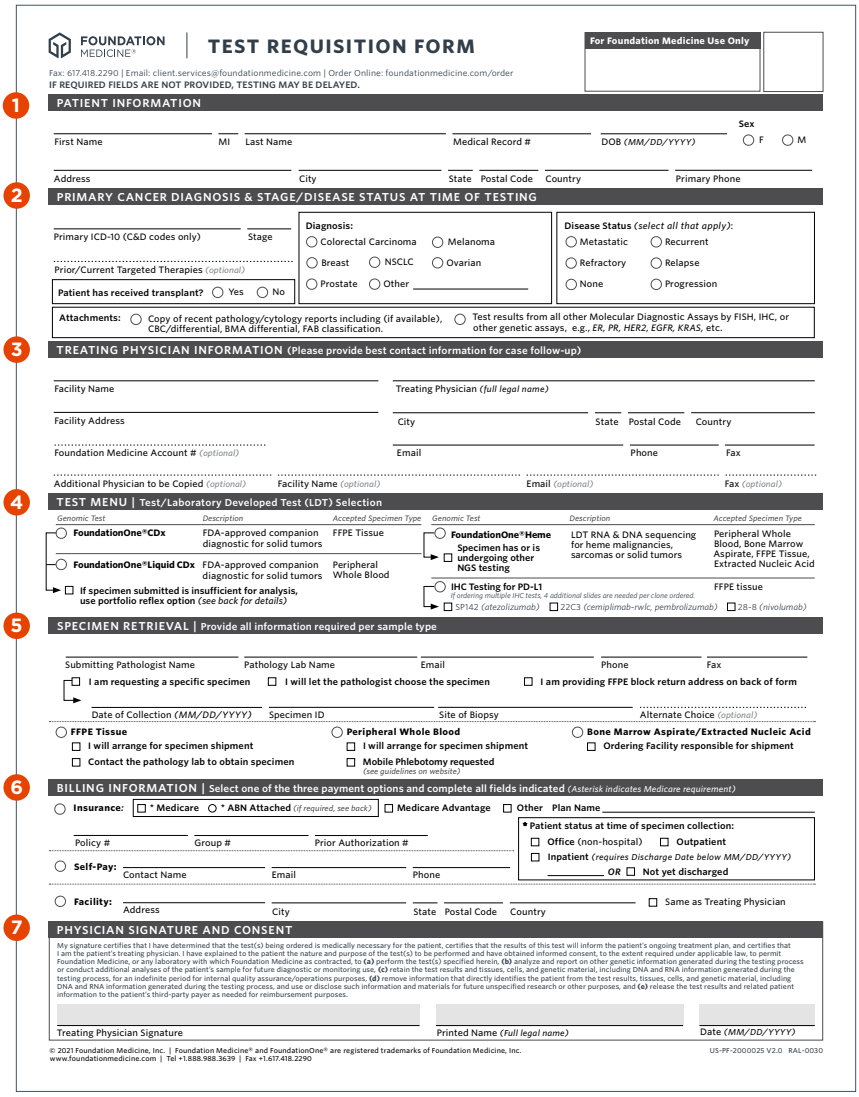
5 Specimen Retrieval Information

Provide information only for the specimen type that is being submitted.

Date of Collection, Specimen ID: All orders submitted require Date of Collection and Specimen ID.

Submitting Pathologist Name, Pathology Lab Name, Phone, Fax, Email: Foundation Medicine may need to contact your submitting pathologist to obtain the sample. Providing contact information will ensure that we can request and receive the sample in a timely manner.

Block Return Address: If you would like FMI to return the FFPE block to you, please indicate the return address on the back of this form.



FOUNDATION MEDICINE®

TEST REQUISITION FORM

For Foundation Medicine Use Only

Fax: 617.418.2290 | Email: client.services@foundationmedicine.com | Order Online: foundationmedicine.com/order
IF REQUIRED FIELDS ARE NOT PROVIDED, TESTING MAY BE DELAYED.

1 PATIENT INFORMATION

First Name | MI | Last Name | Medical Record # | DOB *(MM/DD/YYYY)* | Sex ○ F ○ M

Address | City | State | Postal Code | Country | Primary Phone

2 PRIMARY CANCER DIAGNOSIS & STAGE/DISEASE STATUS AT TIME OF TESTING

Primary ICD-10 (C&D codes only) | Stage

Prior/Current Targeted Therapies *(optional)*

Patient has received transplant? ○ Yes ○ No

Diagnosis:
○ Colorectal Carcinoma ○ Melanoma
○ Breast ○ NSCLC ○ Ovarian
○ Prostate ○ Other

Disease Status *(select all that apply)*:
○ Metastatic ○ Recurrent
○ Refractory ○ Relapse
○ None ○ Progression

Attachments: ○ Copy of recent pathology/cytology reports including (if available), CBC/differential, BMA differential, FAB classification. ○ Test results from all other Molecular Diagnostic Assays by FISH, IHC, or other genetic assays, e.g., *ER, PR, HER2, EGFR, KRAS,* etc.

3 TREATING PHYSICIAN INFORMATION (Please provide best contact information for case follow-up)

Facility Name | Treating Physician *(full legal name)*

Facility Address | City | State | Postal Code | Country

Foundation Medicine Account # *(optional)* | Email | Phone | Fax

Additional Physician to be Copied *(optional)* | Facility Name *(optional)* | Email *(optional)* | Fax *(optional)*

4 TEST MENU | Test/Laboratory Developed Test (LDT) Selection

Genomic Test	Description	Accepted Specimen Type
○ **FoundationOne®CDx**	FDA-approved companion diagnostic for solid tumors	FFPE Tissue
○ **FoundationOne®Liquid CDx**	FDA-approved companion diagnostic for solid tumors	Peripheral Whole Blood
☐ **If specimen submitted is insufficient for analysis, use portfolio reflex option** *(see back for details)*		

Genomic Test	Description	Accepted Specimen Type
○ **FoundationOne®Heme** ☐ **Specimen has or is undergoing other NGS testing**	LDT RNA & DNA sequencing for heme malignancies, sarcomas or solid tumors	Peripheral Whole Blood, Bone Marrow Aspirate, FFPE Tissue, Extracted Nucleic Acid
○ **IHC Testing for PD-L1** *If ordering multiple IHC tests, 4 additional slides are needed per clone ordered.* ☐ SP142 *(atezolizumab)* ☐ 22C3 *(cemiplimab-rwlc, pembrolizumab)* ☐ 28-8 *(nivolumab)*		FFPE tissue

5 SPECIMEN RETRIEVAL | Provide all information required per sample type

Submitting Pathologist Name | Pathology Lab Name | Email | Phone | Fax

☐ **I am requesting a specific specimen** ☐ **I will let the pathologist choose the specimen** ☐ **I am providing FFPE block return address on back of form**

Date of Collection *(MM/DD/YYYY)* | Specimen ID | Site of Biopsy | Alternate Choice *(optional)*

○ **FFPE Tissue**
☐ **I will arrange for specimen shipment**
☐ **Contact the pathology lab to obtain specimen**

○ **Peripheral Whole Blood**
☐ **I will arrange for specimen shipment**
☐ **Mobile Phlebotomy requested** *(see guidelines on website)*

○ **Bone Marrow Aspirate/Extracted Nucleic Acid**
☐ **Ordering Facility responsible for shipment**

6 BILLING INFORMATION | Select one of the three payment options and complete all fields indicated *(Asterisk indicates Medicare requirement)*

○ **Insurance:** ☐ *** Medicare** ○ *** ABN Attached** *(if required, see back)* ☐ **Medicare Advantage** ☐ **Other** **Plan Name**

Policy # | Group # | Prior Authorization #

*** Patient status at time of specimen collection:**
☐ **Office** (non-hospital) ☐ **Outpatient**
☐ **Inpatient** *(requires Discharge Date below MM/DD/YYYY)*
_____ *OR* ☐ **Not yet discharged**

○ **Self-Pay:** Contact Name | Email | Phone

○ **Facility:** Address | City | State | Postal Code | Country ☐ Same as Treating Physician

7 PHYSICIAN 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. I 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 Foundation Medicine, or any laboratory with which Foundation Medicine as 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, **(c)** retain the test results and tissues, cells, and genetic material, including DNA and RNA information generated during the testing process, for an indefinite period for internal quality assurance/operations purposes, **(d)** remove information that directly identifies the patient from the test results, tissues, 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, and **(e)** release the test results and related patient information to the patient's third-party payer as needed for reimbursement purposes.

Treating Physician Signature | Printed Name *(Full legal name)* | Date *(MM/DD/YYYY)*

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6 Billing Information

READ CAREFULLY TO PREVENT A DELAY IN RECEIVING RESULTS

One of the 3 options (Insurance, Facility, Self-Pay) **must be selected** and all associated information must be provided.

Prior Authorization and ABN Attached: If prior authorization has been obtained, provide the authorization number and fax a copy of the health plan authorization letter if available. If unclear about insurance coverage, please download and fax a signed Advance Beneficiary Notice (ABN) form, which is available on our website.

Patient Status at Time of Collection: If Medicare is selected, patient hospital status at time of sample collection is required.

7 Certificate of Medical Necessity/Consent

Important information regarding the physician's duty to inform the patient about the Foundation Medicine test. Read carefully.

Fax or Email the Test Requistion Form

Once all sections of the Test Requisition Form have been completed, attach all necessary documents and fax to (617) 418-2290 OR email to *client.services@foundationmedicine.com*

TECHNICAL INFORMATION

FOUNDATIONONE®CDx

FoundationOne®CDx is a qualitative next-generation sequencing based *in vitro* diagnostic test for advanced cancer patients with solid tumors and is for prescription use only. The test analyzes 324 genes as well as genomic signatures including microsatellite instability (MSI) and tumor mutational burden (TMB) and is a companion diagnostic to identify patients who may benefit from treatment with specific therapies in accordance with the approved therapeutic product labeling. Additional genomic findings may be reported and are not prescriptive or conclusive for labeled use of any specific therapeutic product. Use of the test does not guarantee a patient will be matched to a treatment. A negative result does not rule out the presence of an alteration. Some patients may require a biopsy. For the complete label, including companion diagnostic indications and important risk information, please visit *http://www.F1CDxLabel.com*

FOUNDATIONONE®LIQUID CDx

FoundationOne®Liquid CDx is for prescription use only and is a qualitative next-generation sequencing based *in vitro* diagnostic test for advanced cancer patients with solid tumors. The test analyzes 324 genes utilizing circulating cell-free DNA and is FDA-approved to report short variants in 311 genes and as a companion diagnostic to identify patients who may benefit from treatment with specific therapies (listed in Table 1 of the Intended Use) in accordance with the approved therapeutic product labeling. Additional genomic findings may be reported and are not prescriptive or conclusive for labeled use of any specific therapeutic product. Use of the test does not guarantee a patient will be matched to a treatment. A negative result does not rule out the presence of an alteration. Patients who are negative for companion diagnostic mutations should be reflexed to tumor tissue testing and mutation status confirmed using an FDA-approved tumor tissue test, if feasible. For the complete label, including companion diagnostic indications and complete risk information, please visit *http://www.F1LCDxLabel.com*

FOUNDATIONONE®HEME

FoundationOne®Heme is a laboratory developed test that combines DNA sequencing of 406 genes and RNA sequencing of 265 genes for patients with hematologic malignancies, sarcomas or solid tumors where sensitive fusion detection is desired. The test can be used by physicians to identify potential targeted therapy options, detect alterations in prognostic genes, and sub-classify sarcoma diagnoses. For more information on FoundationOne Heme, please see its Technical Specifications at *http://www.foundationmedicine.com/heme*

IHC Testing

Scoring and clone utilization for PD-L1 testing is based on FDA-approved indications. Refer to *http://www.foundationmedicine.com/IHC* for information.

MEDICARE COVERAGE SUMMARY

Foundation Medicine tests may be covered by Original Medicare[1] and Medicare Advantage[2].

TEST	CONDITIONS FOR MEDICARE COVERAGE	PATIENT COVERAGE CRITERIA
FoundationOne®CDx **FoundationOne®Liquid CDx**	Covered[3] if all patient coverage criteria are met. ABN required for an Original Medicare beneficiary if they do not meet the patient coverage criteria or if person ordering the test is not a treating physician[4].	i) Patient has been diagnosed with a solid malignant neoplasm; ***AND*** ii) Patient has either recurrent, relapsed, refractory, metastatic, or advanced stage III or IV cancer (only requires one of these to be met); ***AND*** iii) Patient has not been previously tested with the same test using NGS for the same cancer genetic content[6]; ***AND*** iv) Patient has decided to seek further cancer treatment (e.g., therapeutic chemotherapy)
FoundationOne®Heme	Covered[5] if all patient coverage criteria are met. ABN required for an Original Medicare beneficiary if they do not meet the patient coverage criteria or if person ordering the test is not a treating physician[4].	i) Patient has been diagnosed with acute myeloid leukemia (AML), myelodysplastic syndrome (MDS) or myeloproliferative neoplasms (MPN); ***OR*** ii) Patient has a suspected myeloid malignancy with an undefined cytopenia for greater than 4 months, and other possible causes have been reasonably excluded ***AND (both criteria iii and iv below)*** iii) Patient has not previously received or is not currently receiving NGS testing on the specimen for which the test is currently being ordered iv) Patient has not been tested with the same test for the same genetic content[6]

References

1. Medicare administered by federal government.
2. Medicare administered by private insurers.
3. Decision Memo for Next Generation Sequencing (NGS) for Medicare Beneficiaries with Advanced Cancer (CAG-00450R – reference appendix B)
4. A "treating physician" is a physician, as defined in §1861(r) of the Social Security Act, who furnishes a consultation or treats a beneficiary for a specific medical problem, and who uses the results of a diagnostic test in the management of the beneficiary's specific medical problem. More information is available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R80BP.pdf.
5. MolDx Local Coverage Determination (LCD): Next-Generation Sequencing Lab-Developed Tests for Myeloid Malignancies and Suspected Myeloid Malignancies (L38047)
6. Repeat testing (FoundationOne®CDx, FoundationOne®Liquid CDx, or FoundationOne®Heme) after disease progression (i.e., there is evidence of a new malignant growth despite response to a prior targeted therapy) may be covered under the NCD for qualifying Medicare beneficiaries.

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