

Foundation Medicine Requisition Form

Our Test Requisition Form Explained

Instructions for completing the Foundation Medicine Test Requisition Form for all tests are outlined below. These provide a general overview, but please contact Client Services at 888.988.3639 or client.services@foundationmedicine.com for questions or further detail. For more information or to order online, visit www.foundationmedicine.com.

1 Patient Demographics

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

2 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.

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 utilize online ordering.

3 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.

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.

FoundationOne® Liquid Reflex Option: If patient tissue sample is insufficient for FoundationOne® CDx, you may preauthorize Foundation Medicine to proceed with our liquid biopsy test, FoundationOne Liquid. We will work with you and your patient to obtain the necessary blood specimen for testing.

5 Specimen Retrieval Information

Provide information only for the specimen type that is being submitted (if the FoundationOne Liquid reflex option has been selected, additionally provide information for Peripheral Whole Blood).

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.

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.

Test Requisition Form

Please fax to: (617) 418-2290 Email: client.services@foundationmedicine.com
All fields required | For more information or to order online, visit www.foundationmedicine.com/genomic-testing/order

FOUNDATION MEDICINE®

- 1 Patient Demographics**

Last Name: Doe First Name: Jane MI: XXXXXX Medical Record #: 01/01/1959 Sex: F M
Address: 1 Example Road City/State/Postal Code: Anycity, MA 99999 Country: USA Phone (primary): 123-555-1234
- 2 Treating Physician Information**

Facility Name: Hospital ABC Treating Physician (full legal name): Dr. John Smith
Facility Address: 10 Second Street City/State/Postal Code: Anytown, MA 99999 Country: USA
Phone: 111-555-1111 Fax: 111-555-1112 Email: jsmith@hospitalabc.com Account #: XXXXXXX
Additional Physician to be Copied (optional): Dr. Susan Sample Facility Name: Hospital ABC Email: ssample@hospitalabc.com Fax: 678-555-6789
- 3 Current Diagnosis/Patient History**

Diagnosis: NSCLC Melanoma Colorectal Carcinoma Ovarian Breast Other _____
Disease Status (select all that apply): Metastatic Recurrent Refractory Relapse None of these options
Additional Details: Adenocarcinoma of right middle lobe Stage: III ICD Codes (only codes beginning C or D accepted): C342
Transplant Information: N/A Targeted Therapies: Erlotinib
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.
- 4 Test Selection | Select one**

Genomic test Description Accepted Specimen Type
 FoundationOne® CDx FDA-approved companion diagnostic for solid tumors FFPE Tissue
 FoundationOne® Liquid Liquid biopsy for all solid tumors Peripheral Whole Blood
 FoundationOne® Liquid Liquid biopsy for all solid tumors Peripheral Whole Blood
Additional Option: IHC Testing PD-L1 (Scoring and clone utilization based on FDA-approved indications. See back of this document for information.)
- 5 Specimen Retrieval | Only one specimen can be tested per order**

Submitting Pathologist Name: Dr. Joe Bloggs Pathology Lab Name: Hospital ABC Phone: 234-555-6789 Fax: 234-555-6788 Email: jbloggs@hospitalabc.com
 Specific specimen requested Let the submitting pathologist choose specimen
Date of Collection (MM/DD/YYYY): 08/14/2018 Specimen ID: XXXXXXX Specimen Site: Right middle lobe Alternate Choice: _____
 FFPE Tissue: Peripheral Whole Blood: Bone Marrow Aspirate/Extracted Nucleic Acid:
 I will arrange for specimen shipment I will arrange for specimen shipment Ordering Facility responsible for shipment
 Contact the pathology lab to obtain specimen Mobile Phlebotomy requested (see guidelines on website)
- 6 Billing Information | Select one of the three payment options and complete all fields indicated**

Insurance (check one): Medicare Medicare Advantage Other Health Insurance Plan Name: _____
Policy #: XXXXXXX Group #: XXXX Prior Authorization #: _____ ABN Attached
Patient status at time of collection: Office (non-hospital) Outpatient Inpatient (requires discharge date MM/DD/YYYY): 08/20/2018
OR Not yet discharged
 Facility: _____ Address: _____ Same as Treating Physician
 Self-Pay: Contact Name: _____ Phone: _____ Email: _____
- 7 Certificate of Medical Necessity/Consent/Test Authorization and Physician Signature**

My signature constitutes a Certificate of Medical Necessity, certifies that this test information 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 testing to be performed and have obtained informed consent, to the extent legally required, to permit Foundation Medicine to (a) perform the testing specified herein, (b) retain the test results for internal quality assurance/operations purposes, (c) de-identify the test results and use or disclose such de-identified results for future unspecified research or other purposes, and (d) release the test results to the patient's third-party payer as needed for reimbursement purposes. My signature also authorizes Foundation Medicine to select the most appropriate test (pursuant to Foundation Medicine's Change in Test Authorization Policy) based on requisition/pathology information.
Dr. John Smith Treating Physician Signature Date: 08/27/2018
Dr. John Smith Printed Name (Full legal name) Date (MM/DD/YYYY)

© 2018 Foundation Medicine, Inc. | Foundation Medicine® and FoundationOne® are registered trademarks of Foundation Medicine, Inc. MKT-0194-02
www.foundationmedicine.com | Tel +1.888.988.3639 | Fax +1.617.418.2290

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 Advanced 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 Requisition 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

FOUNDATIONONE® CDx

Intended Use FoundationOne®CDx is a next-generation sequencing based *in vitro* diagnostic device for detection of substitutions, insertion and deletion alterations, and copy number alterations in 324 genes and select gene rearrangements, as well as genomic signatures including microsatellite instability (MSI) and tumor mutational burden (TMB) using DNA isolated from formalin-fixed, paraffin-embedded (FFPE) tumor tissue specimens. For the complete Intended Use statement, including companion diagnostic indications, please see the FoundationOne CDx Technical Information page: www.foundationmedicine.com/ficdx.

FOUNDATIONONE® HEME

About the Test FoundationOne®Heme is a comprehensive genomic profiling test for hematologic malignancies and sarcomas. The test is designed to provide physicians with clinically actionable information to help with diagnostic sub-classification, prognosis assessment, and targeted therapeutic selection. Test results provide information about clinically significant alterations, potential targeted therapies, available clinical trials, and quantitative markers that may support immunotherapy clinical trial enrollment. FoundationOne Heme is validated to detect all classes of genomic alterations in more than 400 cancer-related genes. In addition to DNA sequencing, FoundationOne Heme employs RNA sequencing across more than 250 genes to capture a broad range of gene fusions, common drivers of hematologic malignancies and sarcomas.

FOUNDATIONONE® LIQUID

About the Test FoundationOne®Liquid is a blood-based circulating tumor DNA (ctDNA) liquid biopsy test for solid tumors that identifies clinically relevant genomic alterations and provides an assessment of high microsatellite instability, across 70 genes known to be drivers of cancer. This test can assist physicians in identifying treatment options by providing clinically actionable information relevant to diagnosis, risk-stratification and prognosis. Test results provide information about potential targeted therapies and/or clinical trials to better inform treatment decisions.

IHC Testing

For tumors with no CDx indication, Foundation Medicine will perform PD-L1 testing using the Dako PD-L1 22C3 PharmDx assay. More information available at this web link: www.foundationmedicine.com/genomic-testing/order.

For Urothelial Carcinoma (URC), if PD-L1 testing with the Ventana SP142 clone is preferred, please indicate that preference on the test requisition form, via online ordering, or contact our client services team at client.services@foundationmedicine.com or by calling +1 888.988.3639.

Medicare Coverage Summary

Select Foundation Medicine tests are covered¹ by Original Medicare² and Medicare Advantage³.

TEST	CONDITIONS FOR MEDICARE COVERAGE	COVERAGE CRITERIA
FoundationOne CDx	Covered if all coverage criteria are met. Advanced Beneficiary Notice (ABN) required if patient does not meet the 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 stages III or IV cancer (only requires one of these to be met); AND iii) Either Patient has not been previously tested using the same NGS test for the same primary diagnosis of cancer OR Patient is undergoing repeat testing using the same NGS test for a new primary cancer diagnosis made by the treating physician; AND
FoundationOne Liquid	Covered if all coverage criteria are met. ABN required if patient does not meet the coverage criteria or if person ordering the test is not a treating physician.	iv) Patient has decided to seek further cancer treatment (e.g., therapeutic chemotherapy)
FoundationOne Heme	Not covered at this time. Foundation Medicine is working toward future coverage. ABN required for every case.	N/A

References

1. Per the "Decision for Next Generation Sequencing (NGS) for Medicare Beneficiaries with Advanced cancer – CAG-00450N."
2. Medicare administered by federal government.
3. Medicare administered by private insurers.
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>.