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 instructions 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).

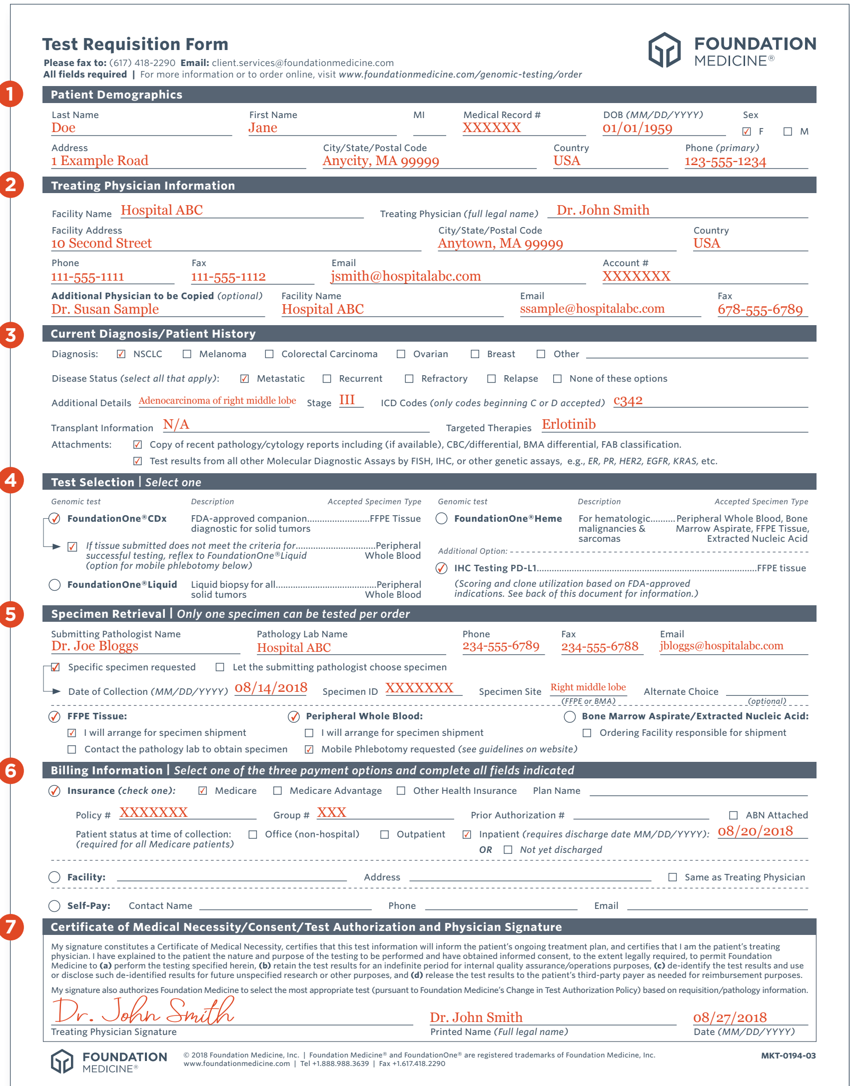
Date of Collection, Specimen ID: All orders submitted require Date of Collection and Specimen ID.

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

FOUNDATION MEDICINE®

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*

1 Patient Demographics

Last Name: Doe | First Name: Jane | MI: | Medical Record #: XXXXXX | DOB *(MM/DD/YYYY)*: 01/01/1959 | Sex: [x] 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: [x] NSCLC [ ] Melanoma [ ] Colorectal Carcinoma [ ] Ovarian [ ] Breast [ ] Other

Disease Status *(select all that apply)*: [x] 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:
[x] Copy of recent pathology/cytology reports including (if available), CBC/differential, BMA differential, FAB classification.
[x] 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
[x] *If tissue submitted does not meet the criteria for successful testing, reflex to FoundationOne®Liquid (option for mobile phlebotomy below)*		Peripheral Whole Blood
( ) **FoundationOne®Liquid**	Liquid biopsy for all solid tumors	Peripheral Whole Blood
( ) **FoundationOne®Heme**	For hematologic malignancies & sarcomas	Peripheral Whole Blood, Bone Marrow Aspirate, FFPE Tissue, Extracted Nucleic Acid

Additional Option:
(✓) **IHC Testing PD-L1** ... FFPE tissue
(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

[x] Specific specimen requested [ ] Let the submitting pathologist choose specimen

Date of Collection *(MM/DD/YYYY)*: 08/14/2018 | Specimen ID: XXXXXXX | Specimen Site *(FFPE or BMA)*: Right middle lobe | Alternate Choice *(optional)*:

(✓) **FFPE Tissue:**
[x] I will arrange for specimen shipment
[ ] Contact the pathology lab to obtain specimen

(✓) **Peripheral Whole Blood:**
[ ] I will arrange for specimen shipment
[x] 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*

(✓) **Insurance** *(check one)*: [x] Medicare [ ] Medicare Advantage [ ] Other Health Insurance | Plan Name:

Policy #: XXXXXXX | Group #: XXX | Prior Authorization #: | [ ] ABN Attached

Patient status at time of collection: *(required for all Medicare patients)* [ ] Office (non-hospital) [ ] Outpatient [x] 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 an indefinite period 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.

Treating Physician Signature: Dr. John Smith | Printed Name *(Full legal name)*: Dr. John Smith | Date *(MM/DD/YYYY)*: 08/27/2018

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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*

FOUNDATION**ONE**® **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/f1cdx.*

FOUNDATION**ONE**® **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.

FOUNDATION**ONE**® **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.

IHC Testing

Foundation Medicine performs PD-L1 IHC testing utilizing the appropriate platform and clone which may be informed by FDA approved companion diagnostic status for the submitted tissue type and diagnosis. More information available at this web link: *www.foundationmedicine.com/genomic-testing/order*.

Medicare Coverage Summary

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

<table>
<tr><th>Test</th><th>Conditions for Medicare Coverage</th><th>Patient Coverage Criteria</th></tr>
<tr><td>FoundationOne®CDx</td><td>Covered[3] if all patient coverage criteria are met. ABN required if patient does not meet the patient coverage criteria or if person ordering the test is not a treating physician[4].</td><td rowspan="2">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
iv) Patient has decided to seek further cancer treatment (e.g., therapeutic chemotherapy)</td></tr>
<tr><td>FoundationOne®Liquid</td><td>Coverage[5] may be available if all patient coverage criteria are met. ABN required if patient does not meet the patient coverage criteria, or if person ordering the test is not a treating physician[4].</td></tr>
<tr><td>FoundationOne®Heme</td><td>Not covered at this time. Foundation Medicine is working toward securing future coverage. ABN required for every case.</td><td>N/A</td></tr>
</table>

References

1. Medicare administered by federal government.
2. Medicare administered by private insurers.
3. Per the "Decision for Next Generation Sequencing (NGS) for Medicare Beneficiaries with Advanced cancer – CAG-00450N
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. National Government Services, the local Medicare Administrative Contractor with jurisdiction over testing performed by Foundation Medicine at its Cambridge, MA laboratory for Original Medicare beneficiaries, does not have a Local Coverage Determination (LCD) for liquid biopsy next generation sequencing >50 genes. Coverage is determined by National Government Services on a case-by-case basis.

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