Foundation Medicine Requisition Form

Our test requisition form explained

Instructions for completing the Foundation Medicine test requisition form for all assays 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 first name (no nicknames) and full legal last name (including any hyphenations).

2 Ordering Physician Information

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".

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. For information on what test is right for your patient, refer to our website or contact Client Services.

FACT Reflex Option: If patient tissue sample is insufficient for FoundationOne® or FoundationOne CDx™, you may preauthorize Foundation Medicine to proceed with our liquid biopsy test, FoundationACT®. 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 FoundationACT reflex option has been selected, additionally provide information for Whole Blood.)

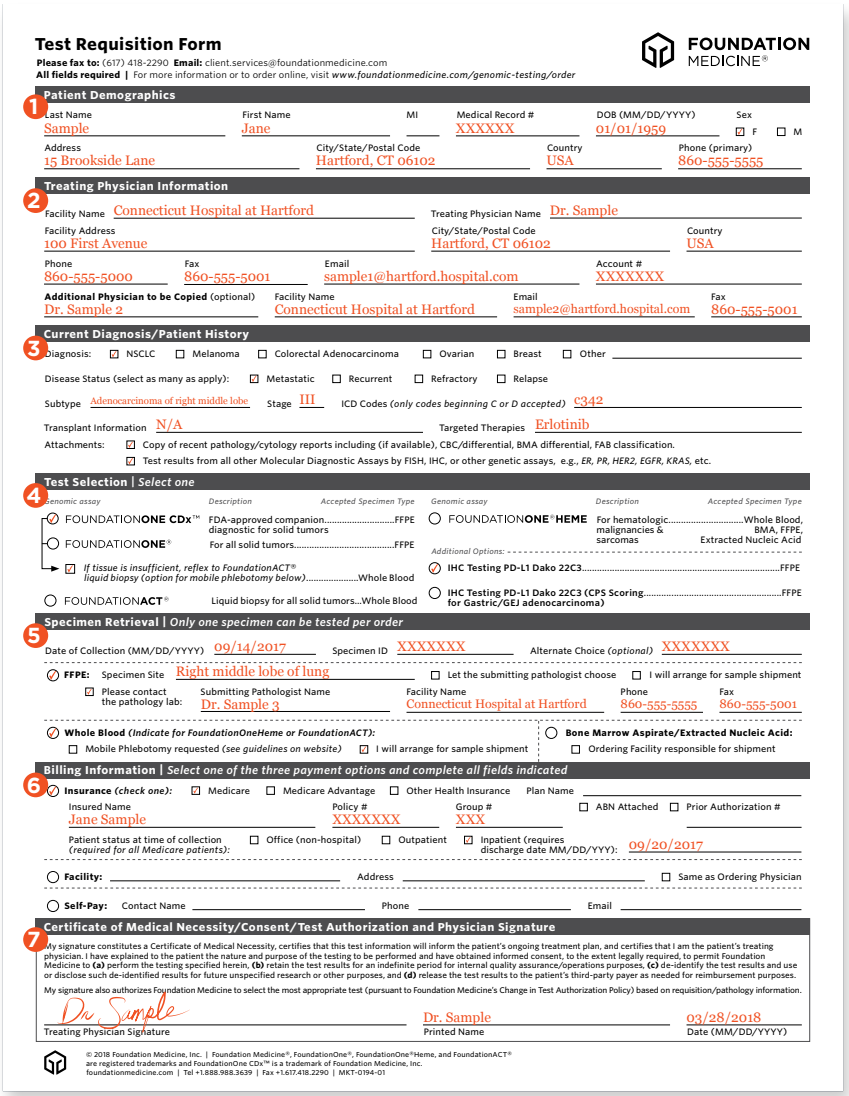
Date of Collection, Specimen ID: All orders submitted require Date of Collection and Specimen ID.

Submitting Pathologist Name, Facility Name, Phone, Fax: 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	First Name	MI	Medical Record #	DOB (MM/DD/YYYY)	Sex
Sample	Jane		XXXXXX	01/01/1959	☑ F ☐ M

Address	City/State/Postal Code	Country	Phone (primary)
15 Brookside Lane	Hartford, CT 06102	USA	860-555-5555

2 Treating Physician Information

Facility Name	Treating Physician Name
Connecticut Hospital at Hartford	Dr. Sample

Facility Address	City/State/Postal Code	Country
100 First Avenue	Hartford, CT 06102	USA

Phone	Fax	Email	Account #
860-555-5000	860-555-5001	sample1@hartford.hospital.com	XXXXXX

Additional Physician to be Copied (optional)	Facility Name	Email	Fax
Dr. Sample 2	Connecticut Hospital at Hartford	sample2@hartford.hospital.com	860-555-5001

3 Current Diagnosis/Patient History

Diagnosis: ☑ NSCLC ☐ Melanoma ☐ Colorectal Adenocarcinoma ☐ Ovarian ☐ Breast ☐ Other

Disease Status (select as many as apply): ☑ Metastatic ☐ Recurrent ☐ Refractory ☐ Relapse

Subtype: 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 assay	Description	Accepted Specimen Type
☑ FOUNDATIONONE CDx™	FDA-approved companion diagnostic for solid tumors	FFPE
☐ FOUNDATIONONE®	For all solid tumors	FFPE
☑ *If tissue is insufficient, reflex to FoundationACT® liquid biopsy (option for mobile phlebotomy below)*		Whole Blood
☐ FOUNDATIONACT®	Liquid biopsy for all solid tumors	Whole Blood

Genomic assay	Description	Accepted Specimen Type
☐ FOUNDATIONONE®HEME	For hematologic malignancies & sarcomas	Whole Blood, BMA, FFPE, Extracted Nucleic Acid

Additional Options:
☑ IHC Testing PD-L1 Dako 22C3 — FFPE
☐ IHC Testing PD-L1 Dako 22C3 (CPS Scoring for Gastric/GEJ adenocarcinoma) — FFPE

5 Specimen Retrieval | *Only one specimen can be tested per order*

Date of Collection (MM/DD/YYYY): 09/14/2017 Specimen ID: XXXXXXX Alternate Choice *(optional)*: XXXXXXX

☑ **FFPE:** Specimen Site: Right middle lobe of lung ☐ Let the submitting pathologist choose ☐ I will arrange for sample shipment

☑ Please contact the pathology lab: Submitting Pathologist Name: Dr. Sample 3 Facility Name: Connecticut Hospital at Hartford Phone: 860-555-5555 Fax: 860-555-5001

☑ **Whole Blood** *(Indicate for FoundationOneHeme or FoundationACT):*
☐ Mobile Phlebotomy requested *(see guidelines on website)* ☑ I will arrange for sample shipment

☐ **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):* ☑ Medicare ☐ Medicare Advantage ☐ Other Health Insurance Plan Name:

Insured Name	Policy #	Group #	☐ ABN Attached	☐ Prior Authorization #
Jane Sample	XXXXXXX	XXX		

Patient status at time of collection *(required for all Medicare patients)*: ☐ Office (non-hospital) ☐ Outpatient ☑ Inpatient (requires discharge date MM/DD/YYY): 09/20/2017

☐ **Facility:** Address: ☐ Same as Ordering 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	Printed Name	Date (MM/DD/YYYY)
Dr Sample	Dr. Sample	03/28/2018

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.

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**®

About the Test FoundationOne® is a validated comprehensive genomic profile (CGP) for solid tumors. The test is designed to provide physicians with clinically actionable information to guide treatment decisions for patients based on the genomic profile of their disease. Test results provide information about clinically significant alterations, potential targeted therapies, available clinical trials, and quantitative markers of response for immunotherapy. FoundationOne is validated to detect all classes of genomic alterations in more than 300 cancer-related genes, including select introns from more than 25 genes often rearranged or altered in solid tumors.

FOUNDATION**ONE®HEME**

About the Test FoundationOne®Heme is a comprehensive genomic profiling assay for hematologic malignancies and sarcomas. The test is designed to provide physicians with clinically actionable information to help with diagnostic subclassification, 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. FoundationOneHeme is validated to detect all classes of genomic alterations in more than 400 cancer-related genes. In addition to DNA sequencing, FoundationOneHeme employs RNA sequencing across more than 250 genes to capture a broad range of gene fusions, common drivers of hematologic malignancies and sarcomas.

FOUNDATION**ACT**®

About the Test FoundationACT® is a blood-based circulating tumor DNA (ctDNA) assay for solid tumors that identifies clinically relevant genomic alterations driving the growth of a patient's cancer. This liquid biopsy can help physicians identify treatment options by providing clinically actionable information relevant to diagnosis, risk-stratification, and prognosis. Test results provide information about potential targeted therapies and/or available clinical trials to better inform treatment decisions. FoundationACT is validated to detect all classes of genomic alterations and to analyze more than 60 of the most commonly mutated genes in solid tumors using only a blood sample.

Summary of Medicare Beneficiary Eligibility based on the Centers for Medicare and Medicaid Services' *Decision Memo for Next Generation Sequencing (NGS) for Medicare Beneficiaries with Advanced Cancer (CAG-00450N)*

FoundationOne CDx™ is covered for Medicare and Medicare Advantage[1] beneficiaries when ordered by a **treating physician**[2] and when all the following clinical conditions are met:

Patient has:

1. A solid malignant neoplasm; **and**
2. Either recurrent, relapsed, refractory, metastatic, or advanced stages III or IV cancer (only requires one of these to be met); **and**
3. Either not been previously tested using the same NGS test for the same primary diagnosis of cancer or repeat testing using the same NGS test only when a new primary cancer diagnosis is made by the treating physician; **and**
4. Decided to seek further cancer treatment (e.g., therapeutic chemotherapy)

Original Advanced Beneficiary Notice (ABN) Requirements: ***https://www.cms.gov/Medicare/Medicare-General-Information/BNI/ABN.html***

Any Original Medicare patient meeting the following criteria will need to provide Foundation Medicine with a signed ABN for Foundation Medicine to perform the following requested service(s):

1. **FoundationOne CDx™** and **FoundationACT®**: ABN required if patient does not meet the above coverage criteria
2. **FoundationOne®**: ABN required if patient does not meet the above coverage criteria and does not have a cancer diagnosis of non-small cell lung cancer (NSCLC)
3. **FoundationOne®Heme**: ABN required for all FoundationOneHeme orders

ABN forms that have been pre-populated with Foundation Medicine's tests/prices can be obtained from:

1. A Foundation Medicine Account Manager
2. Foundation Medicine's online ordering portal
3. Foundation Medicine's website:
   a. Order a Test Page[3]
   b. FoundationOne[4], FoundationOneHeme[5], FoundationACT[6], and FoundationOne CDx[7] product pages
   c. Provider Resources and Patient Resources sites via the above referenced product pages
   d. The FoundationACT and FoundationOneHeme specimen collection and shipping kits

Visit the CMS website[8] and select ***Download the ABN*** to obtain blank ABN forms.

Completed ABN forms can be sent to Foundation Medicine via fax at 866-283-5838 or emailed to *billing@foundationmedicine.com.*

References

1. Chapter 4, § 90.1 of the Medicare Managed Care Manual
2. 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*
3. *https://www.foundationmedicine.com/genomic-testing/order*
4. *https://www.foundationmedicine.com/genomic-testing/foundation-one*
5. *https://www.foundationmedicine.com/genomic-testing/foundation-one-heme*
6. *https://www.foundationmedicine.com/genomic-testing/foundation-act*
7. *https://www.foundationmedicine.com/genomic-testing/foundation-one-cdx*
8. *https://www.cms.gov/Medicare/Medicare-General-Information/BNI/ABN.html*