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®

Patient Demographics

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

Address | City/State/Postal Code | Country | Phone *(primary)*

Treating Physician Information

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

Facility Address | City/State/Postal Code | Country

Phone | Fax | Email | Account #

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

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 _____ Stage _____ ICD Codes *(only codes beginning C or D accepted)* _____

Transplant Information _____ Targeted Therapies _____

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.

Test Selection | *Select one*

Genomic test	*Description*	*Accepted Specimen Type*
○ **FoundationOne®CDx**	FDA-approved companion diagnostic for solid tumors	FFPE Tissue
☐ *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

Genomic test	*Description*	*Accepted Specimen Type*
○ **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.)

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

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

☐ Specific specimen requested ☐ Let the submitting pathologist choose specimen

Date of Collection *(MM/DD/YYYY)* _____ Specimen ID _____ Specimen Site _____ *(FFPE or BMA)* 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

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 # _____ Group # _____ Prior Authorization # _____ ☐ ABN Attached

Patient status at time of collection: ☐ Office (non-hospital) ☐ Outpatient ☐ Inpatient *(requires discharge date MM/DD/YYYY):* _____
(required for all Medicare patients) ***OR*** ☐ *Not yet discharged*

○ **Facility:** _____ Address _____ ☐ Same as Treating Physician

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

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 *(Full legal name)* | Date *(MM/DD/YYYY)*

www.foundationmedicine.com | Tel +1.888.988.3639 | Fax +1.617.418.2290
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Technical Information

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**®**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.

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.

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

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

TEST	CONDITIONS FOR MEDICARE COVERAGE	PATIENT COVERAGE CRITERIA
FoundationOne®CDx	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].	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)
FoundationOne®Liquid	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].	
FoundationOne®Heme	Not covered at this time. Foundation Medicine is working toward securing future coverage. ABN required for every case.	N/A

References

1. Medicare administered by federal government.
2. Medicare administered by private insurers.
3. Per the "Decision for Next Generation Sequencing (NGS) for Medicare Beneciaries 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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