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.

PATIENT INFORMATION

First Name	MI	Last Name	Medical Record #
DOB (MM/DD/YYYY)	Sex ☐ F ☐ M	Address	
City	State	Postal Code	Country	Primary Phone

PATIENT HISTORY *Please provide primary cancer diagnosis and stage/disease status at time of testing*

Primary ICD-10 *(C&D codes only)*

Stage at time of testing:

Patient has received a transplant? ☐ Yes ☐ No

Disease status at time of testing *(select all that apply)*

☐ Metastatic ☐ Recurrent ☐ Relapsed ☐ Refractory ☐ None

Prior/Current Targeted Therapies *(optional)*:

Disease Progression if Tested Previously: ☐ Yes ☐ No

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.

Diagnosis:

☐ Breast ☐ NSCLC ☐ Ovarian ☐ Melanoma ☐ Prostate

☐ Colorectal Carcinoma ☐ Other _____

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	Email
Phone	Fax	Foundation Medicine Account # *(optional)*
Additional Physician to be Copied *(optional)*	Facility Name *(optional)*	Email *(optional)*	Fax *(optional)*

Is the facility a hospital, hospital outpatient department, critical access hospital or ambulatory surgical center? *(see back)* ☐ No ☐ Yes →

If yes, what is the facility's network status with the patient's insurance plan?

☐ In-Network ☐ Out-of-Network ☐ Unknown

TEST MENU *Test/Laboratory Developed Test Selection*

Genomic Test	*Accepted Specimen Types*
☐ **FoundationOne®CDx**	**FFPE TISSUE**
☐ **FoundationOne®Liquid CDx**	**PERIPHERAL WHOLE BLOOD**
☐ **If specimen submitted is insufficient for analysis, use portfolio reflex option** *(see back for details)*	
☐ **FoundationOne®Heme**	**PERIPHERAL WHOLE BLOOD, BONE MARROW ASPIRATE, FFPE TISSUE, EXTRACTED NUCLEIC ACID**
☐ **Specimen has or is undergoing other NGS testing**	
☐ **IHC Testing for PD-L1**	**FFPE TISSUE**

If ordering multiple IHC clones, 4 additional slides are needed per clone ordered.

☐ SP142 *(atezolizumab)* ☐ 22C3 *(cemiplimab-rwlc, pembrolizumab)* ☐ 28-8 *(nivolumab)*

SPECIMEN RETRIEVAL *Provide all information required per sample type*

☐ **FFPE TISSUE**

☐ I will arrange for specimen shipment ☐ Contact Pathology Lab to obtain specimen ☐ I am providing FFPE block return address on back of form

Submitting Pathologist Name	Pathology Lab Name	
Email	Phone	Fax
Date of Collection *(MM/DD/YYYY)*	Specimen ID	Specimen Site	Alternate Choice *(optional)*

☐ **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 ☐ I am requesting a specific specimen ☐ I will let the pathologist choose the specimen

☐ **OTHER** ☐ I am requesting a specific specimen ☐ I will let the pathologist choose the specimen

PATIENT BILLING INFORMATION *Select only one payment option and complete all fields indicated (Asterisk indicates Medicare requirement)*

☐ **Medicare – Part B** ☐ *ABN attached if required *(see back)* | Medicare Policy ID | Patient Status at time of specimen collection* ☐ Hospital Outpatient ☐ Office (Non-Hospital) ☐ Hospital Inpatient – Discharge Date ___/___/____ OR ☐ Not yet discharged

☐ **Other Insurance** | Plan Name | Policy # | Group # | Prior Authorization #

☐ **Self-Pay/Uninsured** | Contact Name | Email | Phone

☐ **Hospital/Institution** ☐ Same as treating physician | Address | City | State | Zip

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 has 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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FFPE BLOCK RETURN INFORMATION

Return Address			
City	State	Postal Code	Country
Email	Phone	Fax	

OTHER INFORMATION

For information on ICD codes, visit this website:
https://icd10cmtool.cdc.gov/

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 foundationmedicine.com/order for more information.

Additional Case Information *(optional)*

TECHNICAL INFORMATION

FOUNDATION**ONE**®**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 *www.F1CDxLabel.com*

FOUNDATION**ONE**®**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 *www.F1LCDxLabel.com*

FOUNDATION**ONE**®**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 RNA sequencing 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 *www.foundationmedicine.com/heme*

IHC Testing

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

FACILITY INFORMATION

This information will be used by Foundation Medicine to determine if the test(s) performed may result in a bill that is affected by surprise billing laws.

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) or for additional primary cancer diagnosis may be covered under the NCD for qualifying Medicare beneficiaries.

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