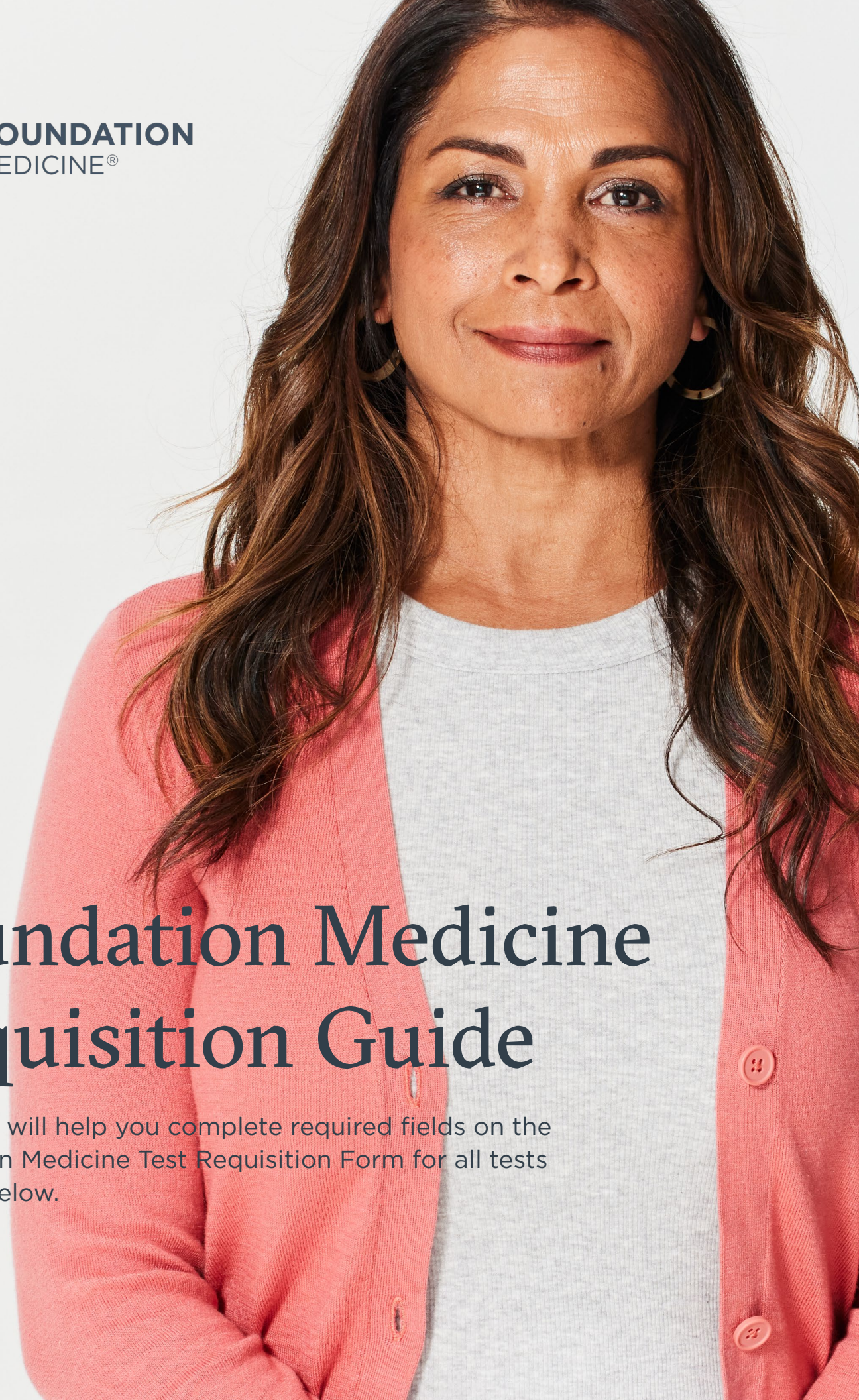
FOUNDATION MEDICINE®



# Foundation Medicine Requisition Guide

This guide will help you complete required fields on the Foundation Medicine Test Requisition Form for all tests outlined below.

For quicker test requisitions, visit the Foundation Medicine portal or order directly through your EMR with our integrations with leading EMR vendors like Epic and OncoEMR.
To sign up and order testing online, visit home.foundationmedicine.com/signup.
For more information on EMR integrations, connect with your Account Executive.

**The most updated form can always be found at foundationmedicine.com.**

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

2 **Current Diagnosis & Patient History**
**To prevent delay in receiving results, to the best of your ability, please include:** Stage AND disease status AND diagnosis and ICD Code(s)
**(See page 2 for details)**

3 **Billing Information**
Please select one of the four options (Medicare - Part B, Insurance/Medicare Advantage, Self-Pay/ Uninsured, Hospital/Institution). Please provide this information accurately to prevent any delay in receiving results.
**(See page 2 for details)**

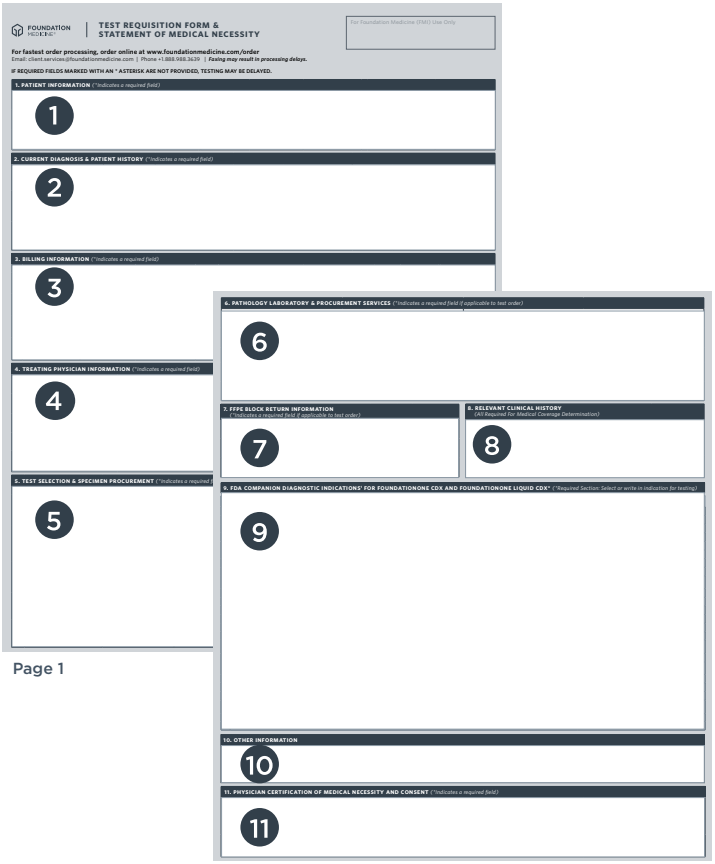
4 **Treating Physician Information**
**Treating Physician Name:** Please provide the full legal name of the treating physician. The name must match the signature at the bottom of page 2.

**Additional Physician to be Copied:** If you would like another physician to get a copy of the report, let us know here. They'll receive it when it's ready. For more physicians, you can easily add them through our online ordering system.
**(See page 2 for details)**

5 **Test Selection & Specimen Procurement**
Please choose one test, unless you are considering additional IHC testing. To find the most suitable test for your patient, check our website or reach out to Client Services.
**(See page 2 for details)**

6 **Pathology Laboratory & Procurement Services**
Please share details only for the type of specimen you're sending. Include the Date of Collection and Specimen ID with every order. For faster processing, please provide: Submitting Pathologist's Name, Pathology Lab Name, Phone, Fax, Email.

7 **FFPE Block Return Information**
If you would like us to return the FFPE block to you, please specify the return address here.



Page 1

Page 2

8 **Relevant Clinical History**
Please add any relevant clinical history here

9 **FDA Companion Diagnostic Indications¹ for FoundationOne®CDx and FoundationOne®Liquid CDx**
Please select the indication being sent for testing. If there are indications that are not listed, but are applicable, please write them in. (For a complete gene list, please visit our website).

10 **Other Information**
Refer here for more information on ICD-10 codes and the Portfolio Reflex Option.

11 **Physician Certification of Medical Necessity and Consent**
Please be sure to complete both printed and signature sections.

# Additional Detailed Information

2 **Diagnosis**
Please specify the current cancer type or select "other." Supplementary information may be added in the "Additional Details" section.

**Attachments**
To help our pathologists better assess the case, consider attaching supplementary test results. Scanning and including them with your submission is recommended. Using our online ordering system can make this process easier. Contact your representative for more details.

3 **Prior Authorization and ABN Attached**
If you have obtained prior authorization, great! Please share the authorization number and health plan letter, if available. If you're unsure about insurance coverage, you can download and send a signed Advance Beneficiary Notice (ABN) form available from our website.

It's easy to reach us: For any and all documents, you may fax, email Client Services, or submit them as an attachment via the online portal.

**Patient Status at Time of Collection**
For Medicare patients, we need to know the patient's hospital status at the time of sample collection.

4 **Foundation Medicine Account Number**
If you don't have an account number, don't worry—Foundation Medicine will make one for you when we get your order.

5 **Portfolio Reflex Option**
Please reference Section 10 in the Foundation Medicine Test Requisition Form for more information on the Portfolio Reflex Option.

## Questions?

We would be happy to hear from you! Feel free to reach out to our **Client Services** team at (888)-988-3639, or email us at client.services@foundationmedicine.com for more information.

You can submit orders via fax (617-418-2290), or by emailing client.services@foundationmedicine.com.

If you would like more information on how to order, please visit us at foundationmedicine.com/info/detail/order-a-test.

## TECHNICAL INFORMATION

**Visit Our Testing Portfolio Here:** *https://www.foundationmedicine.com/portfolio*

### 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.

- Dako 22C3 with Combined Positive Score (CPS) scoring (KEYTRUDA®): Cervical Cancer, HNSCC, ESCC, TNBC
- Dako 22C3 with Tumor Proportion Score (TPS) scoring (KEYTRUDA®, LIBTAYO®): NSCLC
- Dako 28-8 with Tumor Cell Expression scoring (OPDIVO®, YERVOY®): NSCLC
- VENTANA SP142 with Tumor Cell (TC) and Immune Cell (IC) scoring (TECENTRIQ®): NSCLC
- VENTANA SP263 with Tumor Cell (TC) scoring (TECENTRIQ®, LIBTAYO®): NSCLC
- Dako 22C3 with TPS/CPS for other tumors
- VENTANA FOLR1 (ELAHERE™): epithelial ovarian, fallopian tube, or primary peritoneal cancer

## CERTIFICATION AND ACCREDITATION

*https://www.foundationmedicine.com/resource/licenses*

## 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[4] and Medicare Advantage[5])

| TEST | CONDITIONS FOR MEDICARE COVERAGE | PATIENT COVERAGE CRITERIA |
|---|---|---|
| FoundationOne®CDx<br>FoundationOne®Liquid CDx | Covered[6] 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[7]. | **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[9]; *AND* **iv)** Patient has decided to seek further cancer treatment (e.g., therapeutic chemotherapy) |
| FoundationOne®Heme | Covered[8] 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[7]. | **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[9] |


**References:**

1. For the most current information about the therapeutic products in this group, go to: https://www.fda.gov/medical-devices/in-vitro-diagnostics/list-cleared-or-approved-companion-diagnostic-devices-in-vitro-and-imaging-tools
2. Please reference the US Food & Drug Administration website for a current list of cleared or approved companion diagnostic devices and associated therapies: https://www.fda.gov/medical-devices/in-vitro-diagnostics/list-cleared-or-approved-companion-diagnostic-devices-in-vitro-and-imaging-tools
3. Inclusive of the targeted therapies listed and others for which FoundationOne CDx and/or FoundationOne Liquid CDx may be an FDA-approved companion diagnostic in the future
4. Medicare administered by federal government.
5. Medicare administered by private insurers.
6. Decision Memo for Next Generation Sequencing (NGS) for Medicare Beneficiaries with Advanced Cancer (CAG-00450R – reference appendix B).
7. 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.
8. MolDx Local Coverage Determination (LCD): Next-Generation Sequencing Lab-Developed Tests for Myeloid Malignancies and Suspected Myeloid Malignancies (L38047).
9. 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.


FOUNDATION MEDICINE®



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