FOUNDATIONONE®HEME

Comprehensive Genomic Profiling with DNA and RNA

WHAT IS
FOUNDATION**ONE**®**HEME**?

FoundationOne Heme is a comprehensive genomic profiling (CGP) test combining DNA sequencing of 406 genes and RNA sequencing of 265 genes for patients with hematologic malignancies, sarcomas or solid tumors where fusion detection is desired.[1]

FoundationOne Heme is a Laboratory Developed Test.

Valuable insights that may help inform or change treatment plans

FoundationOne Heme can be used by physicians to identify targeted therapy options, detect alterations in prognostic genes, and sub-classify sarcoma diagnoses.

SARCOMA SUB-CLASSIFICATION

Confirming sarcoma subtype based on genomic alterations

PROGNOSTIC GENES

Informing patient risk status based on molecular abnormalities

TARGETED THERAPY OPTIONS

Identifying alterations which may confer sensitivity or resistance to targeted therapies

FoundationOne Heme

For patients with hematologic malignancies, sarcomas or solid tumors where fusion detection is desired.

SARCOMAS

80+

sarcoma subtypes, making sub-classification difficult.[2]

FoundationOne Heme's DNA and RNA sequencing provides sensitive detection of known, novel and complex fusion events. We also have one of the largest databases of sequenced sarcoma patients in the world. (>14K patients sequenced).[3]

LEUKEMIAS

91%

of AML cases had a clinically-relevant genomic alteration.

The FoundationOne Heme panel contains all genes with prognostic implications in AML, including *KIT*, *FLT3* (*ITD* and *TKD*), *NPM1*, *CEBPA*, *IDH1/2*, *RUNX1*, and *ASXL1*.

Of >1600 AML cases sequenced with FoundationOne Heme, 91% of cases had a clinically-relevant genomic alteration, with 62% harboring a genomic alteration in a gene included in professional guidelines.[4,5]

MDS

20

professional guideline-recommended genes with prognostic implications in MDS.[6]

Should a diagnostic workup by FISH test return inconclusive results, FoundationOne Heme can be used, as it includes all 20 of these genes.

Separately, a study of 944 MDS patients found >89% to harbor at least one genomic alteration potentially implicated in establishment of underlying clonal hematopoiesis.[7]

MPN

55%

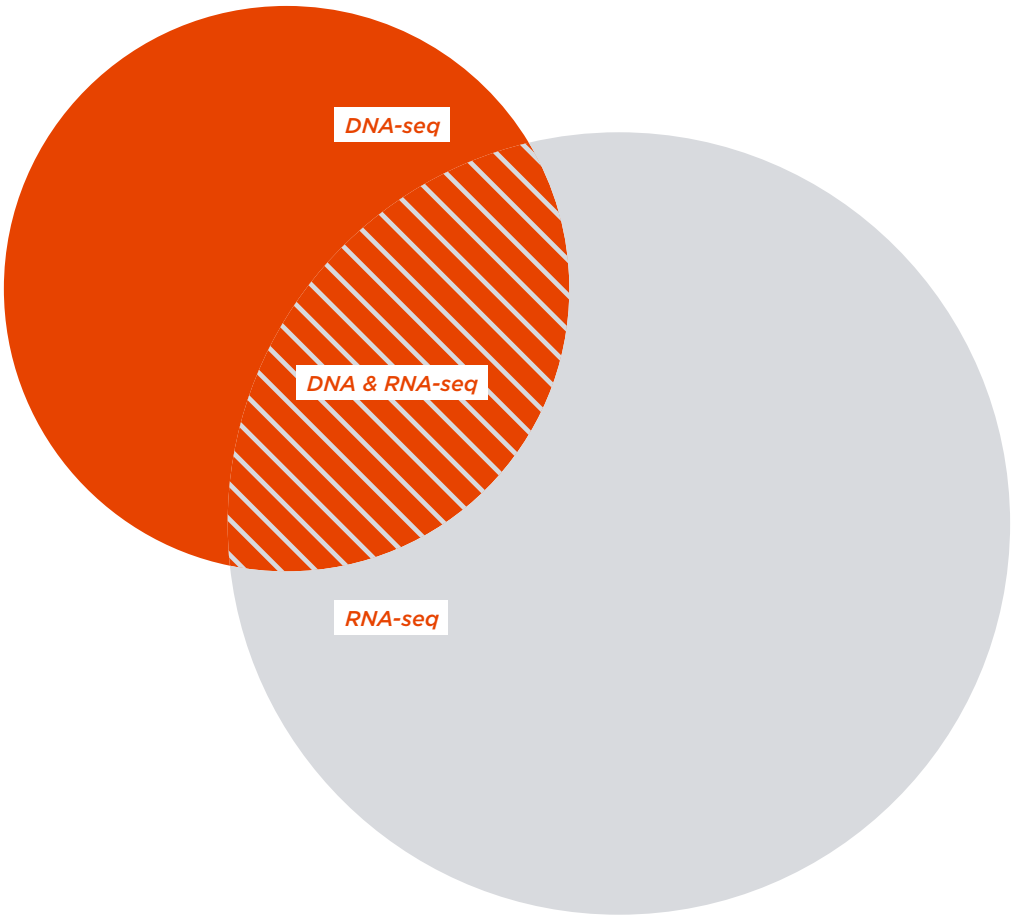
of triple negative MPNs had a clinically relevant alteration.

48% of MPN cases tested with FoundationOne Heme are negative for *CALR*, *JAK2*, and *MPL*. Of these triple negative cases, 55% contained another clinically-relevant genomic alteration.[8]

If results from single biomarker testing are inconclusive for these three genes, FoundationOne Heme sequences >400 more genes to help identify other potential drivers.

FoundationOne Heme interrogates both DNA and RNA

Fusion detection in FoundationOne Heme for select genes



Gene fusions and rearrangements are hallmarks of certain hematologic malignancies and sarcomas. They are also becoming increasingly important in solid tumors. By combining DNA and RNA sequencing, FoundationOne Heme can detect these alterations.[9]

DNA-seq

DNA sequencing identifies 4 types of genomic alterations:

- Base pair substitutions
- Insertions and/or deletions
- Rearrangements
- Copy number alterations (homozygous deletions or amplifications)

Common Rearrangements Detected with DNA sequencing:

(IGH-MYC, IGH-BCL2, IGH-BCL6)

RNA-seq

RNA sequencing also identifies the common genomic alterations and additionally enables efficient detection of known, rare, and novel fusions.

Examples of Novel or Uncommon Fusions/Isoforms:

(MYST3-CREBBP, P2RY8-CRLF2, PAX5-FLII BCR-ABLI, ETV6-ABLI, ETV6-EVI1)

BOTH

FoundationOne Heme is able to detect and confirm complex rearrangements by combining DNA and RNA sequencing data.

Common Rearrangements Detected with Both DNA and RNA Sequencing:

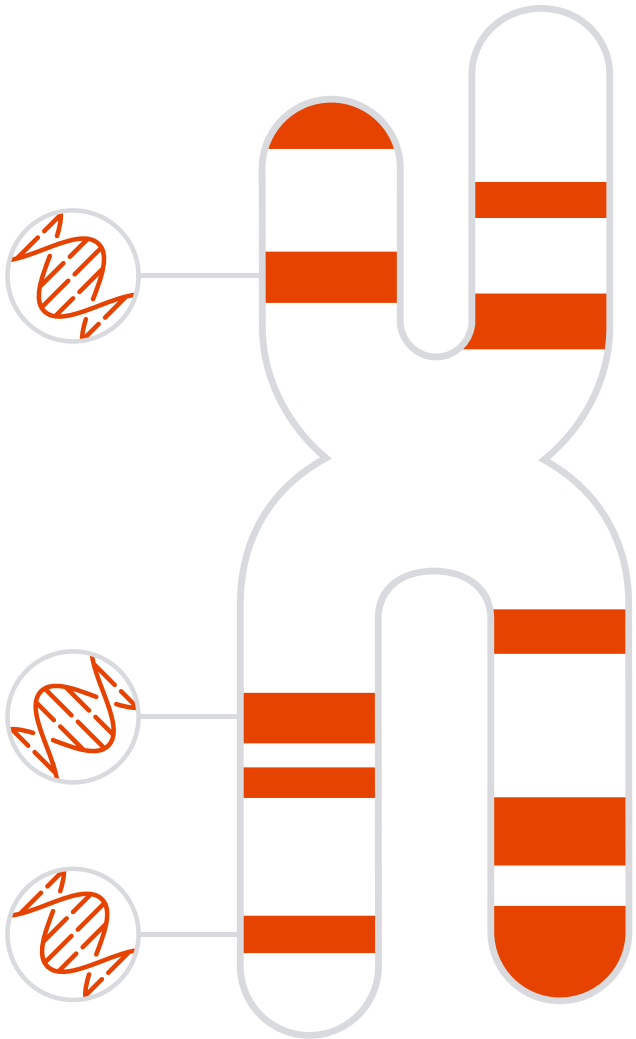
(BCR-ABLI, PML-RARA, MLL Partial Tandem Duplication)

FoundationOne Heme reports Microsatellite Instability (MSI) and Tumor Mutational Burden (TMB)

In solid tumors (including sarcomas), TMB and MSI can confer sensitivity to certain checkpoint inhibitors.[10]

As more hematologic malignancies are evaluated for response to immunotherapy, the consideration of multiple biomarkers, including MSI and TMB, may become standard practice.

FoundationOne Heme includes TMB and MSI scores on all patient reports.



Genomic testing that can be integrated into your practice workflow

MULTIPLE SAMPLE TYPES ACCEPTABLE FOR TESTING

FoundationOne Heme is validated on multiple sample types—peripheral whole blood, bone marrow aspirate, extracted DNA/RNA, and formalin-fixed paraffin-embedded (FFPE) tissue—with a minimum tumor/lesional content of 20% for optimal analysis.

HIGH-TOUCH CLINICAL SUPPORT

Each case is curated and personalized by a team of scientists to ensure all literature and supporting data is kept up-to-date. All reports are reviewed and signed by a board-certified pathologist. We also provide on-call assistance from Physicians, Medical Science Liaisons, and Subject Matter Experts.

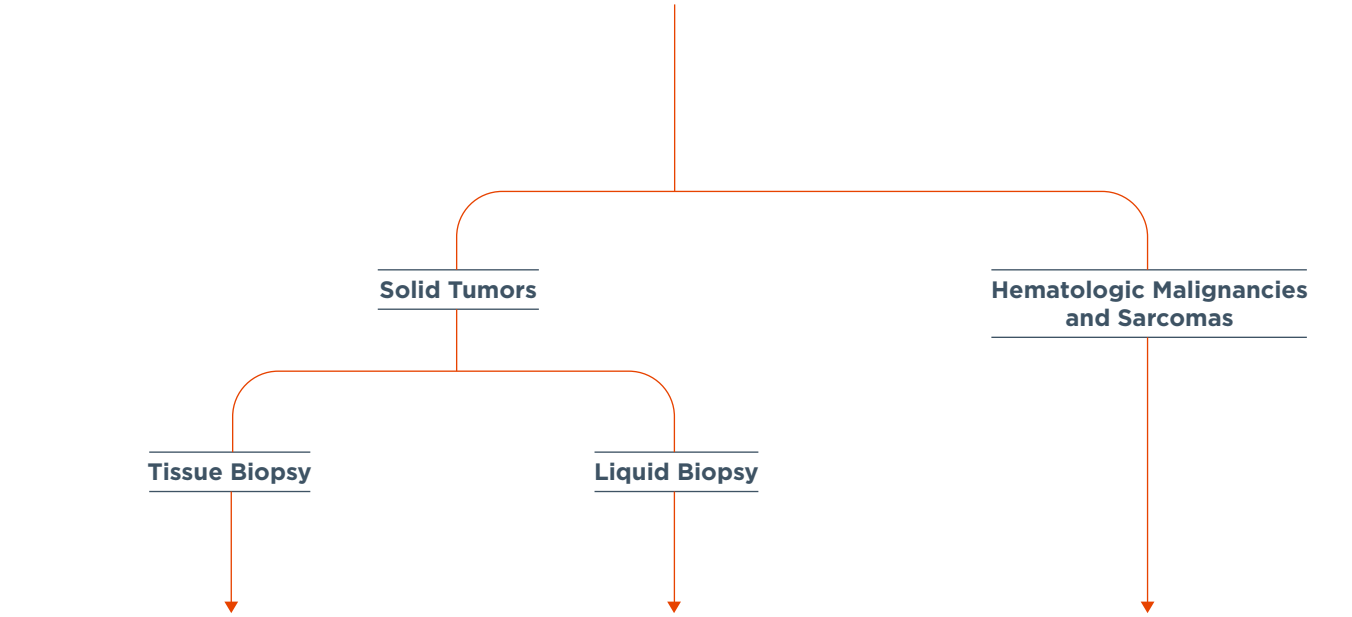
ONLINE PORTAL

The Foundation Medicine Online Portal allows you to place orders digitally, track in-progress tests and view patient reports. Our mobile app offers the same functionality in a convenient format on your phone or tablet

TURN AROUND TIME

FoundationOne Heme reports are typically available within two weeks of specimen receipt at our laboratory.

Foundation Medicine Product Portfolio



FOUNDATIONONE®CDx	FOUNDATIONONE®LIQUID	FOUNDATIONONE®HEME
First FDA-approved comprehensive genomic profiling test across all solid tumors, including companion diagnostic indications for 18 targeted therapies and national coverage for qualifying Medicare and Medicare Advantage patients[11]	A comprehensive genomic profiling test to support targeted therapeutic selection, particularly for patients for whom tissue biopsy is not ideal	A comprehensive genomic profiling (CGP) test combining 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
FDA-Approved	**NY State-Approved Products Performed in a CLIA-Certified Lab** FoundationOne®Heme and FoundationOne®Liquid are laboratory developed tests that were developed and their performance characteristics determined by Foundation Medicine. Neither FoundationOne®Heme or FoundationOne®Liquid have been cleared or approved by the U.S. Food and Drug Administration. For more information on our laboratory developed tests please see their respective Technical Specifications at http://www.foundationmedicine.com	

References

1. FoundationOne®Heme is a laboratory developed test that was developed and its performance characteristics determined by Foundation Medicine. FoundationOne Heme has not been cleared or approved by the U.S. Food and Drug Administration. For more information on FoundationOne Heme, please see its Technical Specifications at http://www.foundationmedicine.com.
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