Technical Specifications

FoundationOne®RNA is a next generation sequencing (NGS) based assay for detection of gene fusions and rearrangements in a broad multigene panel using RNA isolated from formalin-fixed paraffin embedded (FFPE) solid tumor specimens. The assay is intended to provide tumor mutation profiling information for use by qualified healthcare professionals in accordance with professional guidelines in oncology. The assay is performed exclusively at Foundation Medicine, Inc. FoundationOne RNA has not been cleared or approved by the United States Food and Drug Administration (FDA).

Methods

- Uses hybrid capture-based next-generation sequencing technology to detect gene fusions and rearrangements.
- Designed to include genes with somatic alterations in solid tumors that are validated targets for therapy, either approved or in clinical trials, and/or that are unambiguous drivers of oncogenesis based on current knowledge. Genomic findings are not prescriptive or conclusive for labeled use of any specific therapeutic product.
- Analytically validated to employ RNA sequencing across 318 cancer-related genes to capture a broad range of fusions and gene rearrangements.

Testing Process

- All specimens provided for testing are reviewed by a pathologist to ensure specimen viability and tumor content.
- Testing will be performed in a Foundation Medicine laboratory that is accredited by the College of American Pathologists (CAP) and certified by the Clinical Laboratory Improvement Amendments (CLIA).

Reporting

- Test results are provided in an interpretive report, curated by a team of scientists and approved by board-certified and licensed pathologists at Foundation Medicine.
- Test results provide information about clinically significant alterations, potential targeted therapies, and potential available clinical trials.
- Reported alterations may indicate response or lack of response to validated targets for therapy (FDA-approved or in clinical trials), or may be unambiguous drivers of oncogenesis based on reported scientific literature.
- Test results are available via our online portal at www.foundationmedicine.com.*

* Visit foundationmedicine.com to create an online account.

PERFORMANCE CHARACTERISTICS		
Concordance: Gene Fusions and Rearrangements above LoD	Positive percent agreement (PPA)	88.5%
Concordance: Gene Fusions and Rearrangements above LoD	Negative percent agreement (NPA)	99.5%
Concordance: All Gene Fusions and Rearrangements	Positive percent agreement (PPA)	87.2%
Concordance: All Gene Fusions and Rearrangements	Negative percent agreement (NPA)	99.4%
Precision (Reproducibility): Gene Fusions and Rearrangements Detected Above LoD	100%	
Precision (Reproducibility): All Gene Fusions and Rearrangements	94.9%	
Limit of Detection (LoD)	28 reads	
Limit of Blank (LoB)	No gene fusions or rearrangements detected in tumor-adjacent normal FFPE tissue	

Note: Concordance data compares the NovaSeq configuration to the HiSeq configuration. Accuracy study comparing HiSeq configuration to an orthogonal method demonstrated > 90% PPA and > 99% NPA.

Current Gene List →

FoundationOne RNA Gene List

The following genes provide coverage to detect fusions and rearrangements related to RNA.

ABCB1
ABL1
ABL2
ACSL6
AFF1
AFF4
AKT1
AKT2
AKT3
ALK
APC
*AR**
ARHGAP26
ARHGDIA
ARID1A
ARID1B
ASXL1
ATIC
ATM
ATR
AXL
B2M
BAP1
BCL10
BCL11B
BCL2
BCL3
BCL6
BCOR
BCR
BRAF
BRCA1
BRCA2
BRD3
BRD4
BRIP1
BTG1
BTK
CAMTA1
CBFA2T3
CBFB
CBL
CCND1
CCND2
CCND3
CCNE1
CD19
CD274
CD28
CD38
CD74
CDH1
CDK4
CDK6
CDKN2A
CDKN2B
CEBPA
CIC
CIITA
CLDN18
CLDN3
CLTC
CNTRL
COL1A1
CREB3L1
CREB3L2
CREBBP
CRLF2
CSF1
CUX1
CXCR4
CYLD
DDIT3
DDR1
DDR2
DDX10
DEK
DHH
DIRC2
DLC1
DNMT3A
DUSP22
EBF1
*EGFR**
EIF4A2
ELF4
ELL
ELN
EML4
EP300
EPOR
EPS15
ERBB2
ERBB3
ERG
ESR1
ETS1
ETV1
ETV4
ETV5
ETV6
EWSR1
FBXW7
FEV
FGFR1
FGFR1OP
FGFR2
FGFR3
FGFR4
FGR
FLI1
FLT3
FOS
FOSB
FOXO1
FOXO3
FOXO4
FOXP1
FUS
GAS7
GLI1
GLIS2
HDAC10
HERPUD1
HEY1
HIP1
HLF
HMGA1
HMGA2
IGH
IGK
IGL (IGLL5)
IKZF1
IKZF2
IKZF3
INSR
IRF4
ITK
JAK1
JAK2
JAK3
JAZF1
KAT6A
KIF5B
KIT
KMT2A
LATS2
LCP1
LMNA
LMO1
LMO2
LPP
LTK
MAF
MAFB
MALT1
MAML2
MAP3K7
MAP3K8
MAST1
MDS2
MECOM
MEF2C
MEF2D
MEN1
*MET**
MGMT
MKL1
MKL2
MLF1
MLH1
MLLT1
MLLT10
MN1
MNX1
MSH2
MSH6
MSI2
MSMB
MTAP
MTCP1
MYB
MYC
MYH11
NAB2
NBEAP1
NCOA2
NF1
NF2
NIN
NONO
NOTCH1
NOTCH2
NOTCH3
NOTCH4
NPM1
NR4A3
NRAS
NRG1
NRG2
NSD1
NTRK1
NTRK2
NTRK3
NUMA1
NUP214
NUP98
NUTM1
NUTM2A
P2RY8
PALB2
PAX3
PAX5
PAX7
PBX1
PBX3
PDCD1LG2
PDGFB
PDGFD
PDGFRA
PDGFRB
PHF1
PICALM
PIK3CA
PIK3R1
PIK3R2
PKN1
PLAG1
PMS2
PPARG
PRDM16
PRKACA
PRKCA
PRKCB
PRMT5
PTCH1
PTEN
RAF1
RARA
RASGRF1
RB1
RELA
RET
RHOH
ROS1
RPS6KB1
RSPO2
RSPO3
RUNX1
RUNX1T1
SDHA
SDHB
SDHC
SDHD
SEC31A
SEPT5
SEPT6
SEPT7
SET
SH3GL1
SLC45A3
SMAD2
SMAD4
SMARCB1
SNX29
SRC
SS18
SSX1
SSX2
SSX4
STAT6
STIL
STK11
SYK
TAF15
TAL1
TAL2
TBL1XR1
TCF3
TCF4
TCL1A
TCL6
TEC
TERT
TET1
TET2
TFE3
TFEB
TFG
TFPT
THADA
TLX1
TLX3
TMPRSS2
TOP1
TP53
TP63
TPM3
TPM4
TRIM24
TRIP11
TSC1
TSC2
TTL
TYK2
USP6
VHL
WHSC1
WHSC1L1
WT1
WWTR1
YAP1
YWHAE
ZAP70
ZBTB16
ZMYM2
ZNF384
ZNF750

*Coverage includes detection of intragenic splicing or deletion events, specifically AR variant 7, EGFR splice variants (such as EGFR variant III), and MET exon 14 skipping.

FoundationOne®RNA is a laboratory developed test that was developed, and its performance characteristics determined by Foundation Medicine. FoundationOne RNA has not been cleared or approved by the U.S. Food and Drug Administration.

FOUNDATION MEDICINE®

www.foundationmedicine.com | Tel 888.988.3639 | Fax 617.418.2290 | SPEC-01526 V3.0