

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.



FoundationOne RNA Gene List

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

<i>ABCB1</i>	<i>CD19</i>	<i>ERBB2</i>	<i>JAK1</i>	<i>NAB2</i>	<i>PRDM16</i>	<i>TAL2</i>
<i>ABL1</i>	<i>CD274</i>	<i>ERBB3</i>	<i>JAK2</i>	<i>NBEAP1</i>	<i>PRKACA</i>	<i>TBL1XR1</i>
<i>ABL2</i>	<i>CD28</i>	<i>ERG</i>	<i>JAK3</i>	<i>NCOA2</i>	<i>PRKCA</i>	<i>TCF3</i>
<i>ACSL6</i>	<i>CD38</i>	<i>ESR1</i>	<i>JAZF1</i>	<i>NF1</i>	<i>PRKCB</i>	<i>TCF4</i>
<i>AFF1</i>	<i>CD74</i>	<i>ETS1</i>	<i>KAT6A</i>	<i>NF2</i>	<i>PRMT5</i>	<i>TCL1A</i>
<i>AFF4</i>	<i>CDH1</i>	<i>ETV1</i>	<i>KIF5B</i>	<i>NIN</i>	<i>PTCH1</i>	<i>TCL6</i>
<i>AKT1</i>	<i>CDK4</i>	<i>ETV4</i>	<i>KIT</i>	<i>NONO</i>	<i>PTEN</i>	<i>TEC</i>
<i>AKT2</i>	<i>CDK6</i>	<i>ETV5</i>	<i>KMT2A</i>	<i>NOTCH1</i>	<i>RAF1</i>	<i>TERT</i>
<i>AKT3</i>	<i>CDKN2A</i>	<i>ETV6</i>	<i>LATS2</i>	<i>NOTCH2</i>	<i>RARA</i>	<i>TET1</i>
<i>ALK</i>	<i>CDKN2B</i>	<i>EWSR1</i>	<i>LCP1</i>	<i>NOTCH3</i>	<i>RASGRF1</i>	<i>TET2</i>
<i>APC</i>	<i>CEBPA</i>	<i>FBXW7</i>	<i>LMNA</i>	<i>NOTCH4</i>	<i>RB1</i>	<i>TFE3</i>
<i>AR</i>	<i>CIC</i>	<i>FEV</i>	<i>LMO1</i>	<i>NPM1</i>	<i>RELA</i>	<i>TFEB</i>
<i>ARHGAP26</i>	<i>CIITA</i>	<i>FGFR1</i>	<i>LMO2</i>	<i>NR4A3</i>	<i>RET</i>	<i>TFG</i>
<i>ARHGDIA</i>	<i>CLDN18</i>	<i>FGFR10P</i>	<i>LPP</i>	<i>NRAS</i>	<i>RHOH</i>	<i>TFPT</i>
<i>ARID1A</i>	<i>CLDN3</i>	<i>FGFR2</i>	<i>LTK</i>	<i>NRG1</i>	<i>ROS1</i>	<i>THADA</i>
<i>ARID1B</i>	<i>CLTC</i>	<i>FGFR3</i>	<i>MAF</i>	<i>NRG2</i>	<i>RPS6KB1</i>	<i>TLX1</i>
<i>ASXL1</i>	<i>CNTRL</i>	<i>FGFR4</i>	<i>MAFB</i>	<i>NSD1</i>	<i>RSPO2</i>	<i>TLX3</i>
<i>ATIC</i>	<i>COL1A1</i>	<i>FGR</i>	<i>MALT1</i>	<i>NTRK1</i>	<i>RSPO3</i>	<i>TMPRSS2</i>
<i>ATM</i>	<i>CREB3L1</i>	<i>FLI1</i>	<i>MAML2</i>	<i>NTRK2</i>	<i>RUNX1</i>	<i>TOP1</i>
<i>ATR</i>	<i>CREB3L2</i>	<i>FLT3</i>	<i>MAP3K7</i>	<i>NTRK3</i>	<i>RUNX1T1</i>	<i>TP53</i>
<i>AXL</i>	<i>CREBBP</i>	<i>FOS</i>	<i>MAP3K8</i>	<i>NUMA1</i>	<i>SDHA</i>	<i>TP63</i>
<i>B2M</i>	<i>CRLF2</i>	<i>FOSB</i>	<i>MAST1</i>	<i>NUP214</i>	<i>SDHB</i>	<i>TPM3</i>
<i>BAP1</i>	<i>CSF1</i>	<i>FOXO1</i>	<i>MDS2</i>	<i>NUP98</i>	<i>SDHC</i>	<i>TPM4</i>
<i>BCL10</i>	<i>CUX1</i>	<i>FOXO3</i>	<i>MECOM</i>	<i>NUTM1</i>	<i>SDHD</i>	<i>TRIM24</i>
<i>BCL11B</i>	<i>CXCR4</i>	<i>FOXO4</i>	<i>MEF2C</i>	<i>NUTM2A</i>	<i>SEC31A</i>	<i>TRIP11</i>
<i>BCL2</i>	<i>CYLD</i>	<i>FOXP1</i>	<i>MEF2D</i>	<i>P2RY8</i>	<i>SEPT5</i>	<i>TSC1</i>
<i>BCL3</i>	<i>DDIT3</i>	<i>FUS</i>	<i>MEN1</i>	<i>PALB2</i>	<i>SEPT6</i>	<i>TSC2</i>
<i>BCL6</i>	<i>DDR1</i>	<i>GAS7</i>	<i>MET</i>	<i>PAX3</i>	<i>SEPT7</i>	<i>TTL</i>
<i>BCOR</i>	<i>DDR2</i>	<i>GLI1</i>	<i>MGMT</i>	<i>PAX5</i>	<i>SET</i>	<i>TYK2</i>
<i>BCR</i>	<i>DDX10</i>	<i>GLIS2</i>	<i>MKL1</i>	<i>PAX7</i>	<i>SH3GL1</i>	<i>USP6</i>
<i>BRAF</i>	<i>DEK</i>	<i>HDAC10</i>	<i>MKL2</i>	<i>PBX1</i>	<i>SLC45A3</i>	<i>VHL</i>
<i>BRCA1</i>	<i>DHH</i>	<i>HERPUD1</i>	<i>MLF1</i>	<i>PBX3</i>	<i>SMAD2</i>	<i>WHSC1</i>
<i>BRCA2</i>	<i>DIRC2</i>	<i>HEY1</i>	<i>MLH1</i>	<i>PDCD1LG2</i>	<i>SMAD4</i>	<i>WHSC1L1</i>
<i>BRD3</i>	<i>DLC1</i>	<i>HIP1</i>	<i>MLLT1</i>	<i>PDGFB</i>	<i>SMARCB1</i>	<i>WT1</i>
<i>BRD4</i>	<i>DNMT3A</i>	<i>HLF</i>	<i>MLLT10</i>	<i>PDGFD</i>	<i>SNX29</i>	<i>WWTR1</i>
<i>BRIP1</i>	<i>DUSP22</i>	<i>HMGA1</i>	<i>MN1</i>	<i>PDGFRA</i>	<i>SRC</i>	<i>YAP1</i>
<i>BTG1</i>	<i>EBF1</i>	<i>HMGA2</i>	<i>MNX1</i>	<i>PDGFRB</i>	<i>SS18</i>	<i>YWHAE</i>
<i>BTK</i>	<i>EGFR</i>	<i>IGH</i>	<i>MSH2</i>	<i>PHF1</i>	<i>SSX1</i>	<i>ZAP70</i>
<i>CAMTA1</i>	<i>EIF4A2</i>	<i>IGK</i>	<i>MSH6</i>	<i>PICALM</i>	<i>SSX2</i>	<i>ZBTB16</i>
<i>CBFA2T3</i>	<i>ELF4</i>	<i>IGLL5</i>	<i>MSI2</i>	<i>PIK3CA</i>	<i>SSX4</i>	<i>ZMYM2</i>
<i>CBFB</i>	<i>ELL</i>	<i>IKZF1</i>	<i>MSMB</i>	<i>PIK3R1</i>	<i>STAT6</i>	<i>ZNF384</i>
<i>CBL</i>	<i>ELN</i>	<i>IKZF2</i>	<i>MTAP</i>	<i>PIK3R2</i>	<i>STIL</i>	<i>ZNF750</i>
<i>CCND1</i>	<i>EML4</i>	<i>IKZF3</i>	<i>MTCP1</i>	<i>PKN1</i>	<i>STK11</i>	
<i>CCND2</i>	<i>EP300</i>	<i>INSR</i>	<i>MYB</i>	<i>PLAG1</i>	<i>SYK</i>	
<i>CCND3</i>	<i>EPOR</i>	<i>IRF4</i>	<i>MYC</i>	<i>PMS2</i>	<i>TAF15</i>	
<i>CCNE1</i>	<i>EPS15</i>	<i>ITK</i>	<i>MYH11</i>	<i>PPARG</i>	<i>TAL1</i>	

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.

