Technical Specifications

Intended Use

FoundationOne Liquid CDx is a qualitative next generation sequencing based *in vitro* diagnostic test that uses targeted high throughput hybridization-based capture technology to detect and report substitutions, insertions and deletions (indels) in 311 genes, rearrangements in four (4) genes, and copy number alterations in three (3) genes. FoundationOne Liquid CDx utilizes circulating cell-free DNA (cfDNA) isolated from plasma derived from anti-coagulated peripheral whole blood of cancer patients collected in FoundationOne Liquid CDx cfDNA blood collection tubes included in the FoundationOne Liquid CDx Blood Sample Collection Kit. The test is intended to be used as a companion diagnostic to identify patients who may benefit from treatment with the targeted therapies listed in Table 1 in accordance with the approved therapeutic product labeling.

Table 1: Companion diagnostic indications

TUMOR TYPE	BIOMARKER(S) DETECTED	THERAPY
	ALK rearrangements	ALECENSA® (alectinib)
Non-small cell lung cancer (NSCLC)	<i>EGFR</i> Exon 19 deletions and <i>EGFR</i> Exon 21 L858R subsitution	IRESSA® (gefitinib) TAGRISSO® (osimertinib) TARCEVA® (erlotinib)
	<i>MET</i> single nucleotide variants (SNVs) and indels that lead to <i>MET</i> exon 14 skipping	TABRECTA® (capmatinib)
Durchata	BRCA1, BRCA2, ATM alterations	LYNPARZA® (olaparib)
Prostate cancer	BRCA1, BRCA2 alterations	RUBRACA® (rucaparib)
Ovarian cancer	BRCA1, BRCA2 alterations	RUBRACA® (rucaparib)
Breast cancer	<i>PIK3CA</i> mutations C420R, E542K, E545A, E545D [1635G>T only], E545G, E545K, Q546E, Q546R; and H1047L, H1047R, and H1047Y	PIQRAY* (alpelisib)

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Additionally, FoundationOne Liquid CDx is intended to provide tumor mutation profiling to be used by qualified health care professionals in accordance with professional guidelines in oncology for patients with solid malignant neoplasms. A negative result from a plasma specimen does not mean that the patient's tumor is negative for genomic findings. Patients with the tumor types above who are negative for the mutations listed in Table 1 should be reflexed to routine biopsy and their tumor mutation status confirmed using an FDA-approved tumor tissue test, if feasible. Genomic findings other than those listed in Table 1 are not prescriptive or conclusive for labeled use of any specific therapeutic product. FoundationOne Liquid CDx is a single-site assay performed at Foundation Medicine, Inc. in Cambridge, MA.

Summary of Analytical Sensitivity and Specificity for FDA-Approved Content

Results from our Limit of Detection (LoD) study are shown below, indicating the median variant allele frequency or tumor fraction at which the test has shown 95% probability of detection.¹ Results are also included from the Limit of Blank (LoB) study, which evaluated variant calling in healthy donors. Please refer to our product labeling for a list of the 75 genes baited for enhanced sensitivity are noted in bold in the gene list on the next page.

ALTERATION TYPE	BAIT SET REGION	MEDIAN LIMIT OF DETECTION (LOD)	LOD RANGE QUARTILE 1-3*	LIMIT OF BLANK (VARIANT DETECTION RATE IN HEALTHY DONORS) ⁺	
Short Variants	Enhanced Sensitivity	0.40% VAF	0.33% - 0.50% VAF	0.82%	
Snort Variants	Standard Sensitivity	0.82% VAF	0.70% - 0.98% VAF	0.82%	
	Enhanced Sensitivity	0.37% VAF	0.26% - 0.47% VAF	0%	
Rearrangements	Standard Sensitivity	0.90% VAF	NA	0%	
Copy Number Amplifications	NA	21.7% TF	19.8%-25.2% TF	0%	

VAF = variant allele frequency; TF = tumor fraction

 $^{\ast}~$ The accuracy of %VAF / %TF have not been analytically validated

+ Calculated as the number of unique variants detected at least once across all replicates divided by the total number of unique variants included in the analysis



Foundation One Liquid CDx FDA-Approved Gene $\mbox{List}^{\mbox{\tiny t}}$

As part of its FDA-approved intended use, FoundationOne Liquid CDx interrogates 311 genes, including 309 genes with complete exonic (coding) coverage and 2 genes with only select non-coding coverage (indicated with *). **Select genes and select exons (indicated in bold) are captured with increased sensitivity.**

KLHL6KMT2A (MLL)KMT2D (MLL2)KRASLTKLYNMAFMAP2K1 (MEK1)MAP2K2 (MEK2)MAP2K4MAP3K1MAP3K13MAPK1MCL1MDM2MDM4MED12MEF2BMEN1MERTKMETMITFMKNK1MLH1MPL Exon 10MRE11AMSH2MSH3MSH2MSH6MSTIRMTAPMED12METOR Exon 10MCT1METMETMSH6MKNK1MLH1MPL Exon 10MCT1MSH2MSH3MSH3MSH6MSTIRMTAPMTOR Exon 19, 30, 39, 40, 43-45, 47, 48, 53, 56MUTYHMYCMYCL (MYCLT)MSK6MSTRAMBNNFTNF2NFE2L2NFKBIANKX2-1NOTCH1NOTCH2NOTCH3NPM1 Exon 4-6, 8, 10NRAS Exon 2, 3NSD3 (WHSCLE)NT5C2MTRK1 Exon 14, 15NTRK2NTRK3 Exon 61, 7P2RY8PALB2PARK2	ABL1 Exons 4-9	ACVR1B	AKT1 Exon 3	AKT2	AKT3	ALK Exons 20-29, Introns 18, 19	ALOX12B
NAMECAUCHCAURY <td>AMER1 (FAM123B)</td> <td>APC</td> <td>AR</td> <td>ARAF Exons 4, 5, 7, 11, 13, 15, 16</td> <td>ARFRP1</td> <td>ARIDIA</td> <td>ASXL1</td>	AMER1 (FAM123B)	APC	AR	ARAF Exons 4, 5, 7, 11, 13, 15, 16	ARFRP1	ARIDIA	ASXL1
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DOTLEDDEDFAEPROEPROEPROEPHOEPHOEPHOENDLSubstantiantRRC1RRC1RRC1RRC1RRC1RRC1RRC1RRC1ENDLRAGCRAGCRAGCRAGCRAGCRRC2RRC2RGC3RGC3RGC3ENMVFEFORGF1RGF2RGF2RGF3RGC3 </td <td>CXCR4</td> <td>CYP17A1</td> <td>DAXX</td> <td>DDR1</td> <td>DDR2</td> <td>DIS3</td> <td>DNMT3A</td>	CXCR4	CYP17A1	DAXX	DDR1	DDR2	DIS3	DNMT3A
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Event with with with with a set of the set of th	ERBB2	Exons 3, 6, 7, 8, 10, 12,	ERBB4	ERCC4	ERG	ERRFI1	
EGFAE		FAM46C	FANCA	FANCC	FANCG	FANCL	FAS
FLCNICTURFLGN Econs 14, 18, 20FOX 20USBRGARA6GATA6GATA6GATA6GAAA1GAAA2GAAA3GAAA3GAAA3GAAA3GAAA3GATA6GATA6GAAA1GAAA3GAAA3GAAA3GAAA3GAAA3GAAA3GATA6GATA6GAAA1GAAA3GAAA3GAAA3GAAA3GAAA3GAAA3GSK3BGATA6GAAA3GAAA3GAAA3GAAA3GAAA3GAAA3GAAA3GSK3BGATA6GAAA3GAGAGAAA3GAAA3GAAA3GAAA3GAAA3ID3DAGAGAAAGAFAGAAA3GAAA3GAAA3GAAA3GAAA3ID3DAGAGAAAGARAGAAA3GAAA3GAAA3GAAA3GAAA3ID3CMTACGAAACARAACARAAGAAA3GAAA3GAAA3GAAA3GAAA3ID4MATAAMATAAMATAAMAPACIAMAPACIAMAPACIAMACL <td>FBXW7</td> <td>FGF10</td> <td>FGF12</td> <td>FGF14</td> <td>FGF19</td> <td>FGF23</td> <td>FGF3</td>	FBXW7	FGF10	FGF12	FGF14	FGF19	FGF23	FGF3
ExtensionGATAG	FGF4	FGF6	FGFR1	FGFR2	Exons 7, 9 (alternative	FGFR4	FH
General Problem Events 4, 5 Events 4, 6 RS381 GSK380 BCH_1 $BDAC1$ $HGFA$ HFA $HCA2$	FLCN	FLT1		FOXL2	FUBP1	GABRA6	GATA3
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Exons 2-3 Exons 2-4e, 7 MDM2 MDM4 MEDI2 MEF28 MENIA MERTA MERTA MERTA MITF MKNK1 MEIDIA MPL1 Exon 19, 30, 39, 40, 55 MREIIA MSR1A MSR1A MSR1A MSR1A MSH6 MSTR MTAP MTOR Exon 19, 30, 39, 40, 55 MUTYH MYCA MYCL (MYCL) MYCN MYDR 8 MTAP MTOR MUTYH MYCA MYCL (MYCL) MYCN MYDR 8 MTAP MTOR MUTYH MYCA MYCL (MYCL) MYCN MYDR 8 MITA MTRA MTOR MUTYH MYCA MYCL (MYCL) MYCN MYDR 8 MITA MTRA MTRA MITA MITA MITA MITA MYCN MYDR 8 MITA MITA MITA MITA MITA MITA MYCN MYDR 8 MITA MITA MITA MITA MITA MITA MYCN 8 MYTR1 MITA MITA MITA	KLHL6	KMT2A (MLL)	KMT2D (MLL2)	KRAS	LTK	LYN	MAF
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Exrons 19, 30, 39, 40, Exrons 49, 47, 44, 85, 47, 46, 45, 47, 46, 45, 47, 46, 45, 47, 46, 45, 47, 46, 47, 47, 46, 47, 46, 47, 47, 47, 47, 46, 47, 46, 47, 47, 47, 47, 47, 47, 47, 47, 47, 47	MITF	MKNK1	MLH1		MRE11A	MSH2	MSH3
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InterpretationExtend by Extend by Exte		MSTIR					
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PDGFRA Exons 12-21, 23PDK1PIK3C2BPIK3C2GPIK3C4PIK3C4PIK3C4PIK3R1PIM1PMS2POLD1POLEPPARGPP2R1APPP2R2APRDM1PKARIAPKC1PTCH1PTENPTEN1PTPOQK1RAC1RAD21RAD51RAD51BRAD51CRAD51DRAD52RAD54LRAFT Exons 3.4, 6, 7, 10, 14, 19, 27RARARB1RBM10RELRET Exons 11, 13-16RICORRIF43SF3B1SGK1SMAD2SDHBSDHCSDHDSETD2SF3B1SGK1SMAD2SOX9SPENSPOPSRCSTAG2STAT3SOX2SUFUSYKTBX3TEKTEKC* RENATERT* PromoterTET2TGFBR2TIPARPTINFAIP3TIFAPSTET2STAT3SCS1TGFBR2JUARCVEGFATNFRSFI4TPS3SCITSC2TYRO3U2AF1VEGFAVHLWHSC1WT1XP01		MYD88 Exon 4	NBN	43-45, 47, 48, 53, 56 NF1	NPM1	NRAS	NFKBIA NSD3 (WHSC1L1)
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Exons 3, 4, 6, 7, 10, 4, 15, 15ReLRET Exons 1, 13-16RICORRNF43ROS1 Stans 1, 36-38, 40RPORSDHASDHBSDHCSDHDSETD2SF3B1SGK1SMAD2SMAD4SMARCA4SMARCB1SMOSNCAIPASOCS1SOX2SOX9SPENSPOPSRCSTAG2STAT3STK1SUFUSYKIBX3TEKTERC*TERT*TET2*FGFBR2TIPARPNFAIP3NFRSF14FD53TSC1TSC2TYRO3U2AF1VEGFAVHLWHSC1WTXP01	NKX2-1 NT5C2 PARP1 PDGFRA Exons 12, 18 PIK3R1	MYD88 Exon 4 NOTCH1 MTRK1 Exons 14, 15 PARP2 PDGFRB Exons 12-21, 23	NBN NOTCH2 NTRK2 PARP3 PDK1 PMS2	43-45, 47, 48, 53, 56 NF1 NOTCH3 NTRK3 Exons 16, 17 PAX5 PIK3C2B POLD1	NPM1 Exons 4-6, 8, 10 P2RY8 PBRM1 PIK3C2G POLE	NRAS Exons 2, 3 PALB2 PDCDI (PD-1) PIK3CA Exons 2, 3, 5-8, 10, 14,1 9, 21 (Coding Exons 1, 2, 4-7, 9, 13, 18, 20) PPARG	NSD3 (WHSCILI) PARK2 PDCD1LG2 (PD-L2) PIK3CB PPP2RIA
Exons 11, 13-16Exons 31, 36-38, 40SDHBSDHCSDHDSETD2SF3B1SGK1SMAD2SMAD4SMARCA4SMARCB1SMOSNCAIPSOCS1SOX2SOX9SPENSPOPSRCSTAG2STAT3STK11SUFUSYKTBX3TEKTERC* ncRNATERT* PromoterTET2TGFBR2IPARPNFAIP3NIFRSF14TP53TSC1TSC2TYRO3U2AF1VEGFAVHLWHSC1WT1XP01	NKX2-1 NT5C2 PARP1 PDGFRA Exons 12, 18 PIK3R1 PPP2R2A	MYD88 Exon 4 NOTCH1 Exons 14, 15 PARP2 PDGFRB Exons 12-21, 23 PIM1 PRDM1	NBN NOTCH2 NTRK2 PARP3 PDK1 PMS2 PRKAR1A	43-45, 47, 48, 53, 56 NF1 NOTCH3 NTRK3 Exons 16, 17 PAX5 PIK3C2B POLD1 PRKCI	NPM1 Exons 4-6, 8, 10 P2RY8 PBRM1 PIK3C2G POLE PTCH1	NRAS Exons 2, 3 PALB2 PDCDI (PD-1) PIK3CA Exons 2, 3, 5-8, 10, 14, 1 9, 21 (Coding Exons 1, 2, 4-7, 9, 13, 18, 20) PPARG PTEN	NSD3 (WHSCILI) PARK2 PDCD1LG2 (PD-L2) PIK3CB PPP2RIA PTPN11
SMAD4SMARCA4SMARCB1SMOSNCAIPSOCS1SOX2SOX9SPENSPOPSRCSTAG2STAT3STK11SUFUSYKTBX3TEKTERC* FERT* romoterTET2TGFBR2TIPARPTNFAIP3TNFRSF14 TP53 TSC1TSC2TYRO3U2AF1VEGFAVHLWHSC1WT1XP01	NKX2-1 NT5C2 PARP1 PDGFRA Exons 12, 18 PIK3R1 PPP2R2A PTPRO	MYD88 Exon 4 NOTCH1 NTRK1 Exons 14, 15 PARP2 PAGFRB Exons 12-21, 23 PIM1 PRDM1 QKI	NBN NOTCH2 NTRK2 PARP3 PDK1 PMS2 PRKAR1A RAC1	43-45, 47, 48, 53, 56 <i>NF1</i> <i>NOTCH3</i> <i>NTRK3</i> Exons 16, 17 <i>PAX5</i> <i>PIK3C2B</i> <i>POLD1</i> <i>PRKC1</i> <i>RAD21</i> <i>RAF1</i>	NPM1 Exons 4-6, 8, 10 P2RY8 PBRM1 PIK3C2G POLE PTCH1 RAD51 RARA	NRAS Exons 2, 3 PALB2 PDCD1 (PD-1) PIK3CA Exons 2, 3, 5-8, 10, 14,1 9, 21 (Coding Exons 1, 2, 4-7, 9, 13, 18, 20) PPARG PTEN RAD51B	NSD3 (WHSCILI) PARK2 PDCD1LG2 (PD-L2) PIK3CB PPP2RIA PTPN11 RAD51C
SOX9SPENSPOPSRCSTAG2STAT3STK11SUFUSYKTBX3TEKTERC* ncRNATERT* prometerTET2TGFBR2TIPARPTNFAIP3TNFRSF14TP53TSC1TSC2TYRO3U2AF1VEGFAVHLWHSC1WT1XP01	NKX2-1 NT5C2 PARP1 PDGFRA Exons 12, 18 PIK3R1 PPP2R2A PTPRO RAD51D	MYD88 Exon 4 NOTCH1 MTRK1 Exons 14, 15 PARP2 PDGFRB Exons 12-21, 23 PIM1 PRDM1 QK1 RAD52 RET	NBN NOTCH2 NTRK2 PARP3 PDK1 PMS2 PRKAR1A RAC1 RAD54L	43-45, 47, 48, 53, 56 <i>NF1</i> <i>NOTCH3</i> <i>NTRK3</i> Exons 16, 17 <i>PAX5</i> <i>PIK3C2B</i> <i>POLD1</i> <i>PRKCI</i> <i>RAD21</i> <i>RAF1</i> Exons 3, 4, 6, 7, 10, 14, 15, 17	NPM1 Exons 4-6, 8, 10 P2RY8 PBRM1 PIK3C2G POLE PTCH1 RAD51 RARA ROS1	NRAS Exons 2, 3 PALB2 PDCD1 (PD-1) PIK3CA Exons 2, 3, 5-8, 10, 14,1 9, 21 (Coding Exons 1, 2, 4-7, 9, 13, 18, 20) PPARG PTEN RAD51B RB1	NSD3 (WHSCILI) PARK2 PDCDILG2 (PD-L2) PIK3CB PPP2RIA PTPN11 RAD51C RBM10
SUFUSYKTBX3TEKTERC* ncRNA TERT* PromoterTET2TGFBR2TIPARPTNFAIP3TNFRSF14 TP53 TSC1TSC2TYRO3U2AF1 VEGFA VHLWHSC1WT1XP01	NKX2-1 NT5C2 PARP1 PDGFRA Exons 12, 18 PIK3R1 PPP2R2A PTPRO RAD51D REL	MYD88 Exon 4 NOTCH1 MTRK1 Exons 14, 15 PARP2 PDGFRB Exons 12-21, 23 PIM1 PRDM1 QK1 RAD52 RET Exons 11, 13-16	NBN NOTCH2 NTRK2 PARP3 PDK1 PMS2 PRKAR1A RAC1 RAD54L RICTOR	43-45, 47, 48, 53, 56 <i>NF1</i> <i>NOTCH3</i> <i>NTRK3</i> Exons 16, 17 <i>PAX5</i> <i>PIK3C2B</i> <i>POLD1</i> <i>PRKC1</i> <i>RAD21</i> <i>RAF1</i> <i>Exons</i> 3, 4, 6, 7, 10, 14, 15, 17 <i>RNF43</i>	NPM1 Exons 4-6, 8, 10 P2RY8 PBRM1 PIK3C2G POLE PTCH1 RAD51 RARA ROS1 Exons 31, 36-38, 40	NRAS Exons 2, 3 PALB2 PDCD1 (PD-1) PIK3CA Exons 2, 3, 5-8, 10, 14,1 9, 21 (Coding Exons 1, 2, 4-7, 9, 13, 18, 20) PPARG PTEN RAD51B RB1 RPTOR	NSD3 (WHSCILI) PARK2 PDCD1LG2 (PD-L2) PIK3CB PPP2R1A PTPN11 RAD51C RBM10 SDHA
TGFBR2 TIPARP TNFAIP3 TNFRSF14 TP53 TSC1 TSC2 TYRO3 U2AF1 VEGFA VHL WHSC1 WT1 XP01	NKX2-1 NT5C2 PARP1 PDGFRA Exons 12, 18 PIK3R1 PPP2R2A PTPRO RAD51D REL SDHB	MYD88 Exon 4 NOTCH1 NTRK1 Exons 14, 15 PARP2 PDGFR8 Exons 12-21, 23 PIM1 PRDM1 QK1 RAD52 RET Exons 11, 13-16 SDHC	NBN NOTCH2 NTRK2 PARP3 PDK1 PMS2 PRKARIA RAC1 RAD54L RICTOR SDHD	43-45, 47, 48, 53, 56 <i>NF1</i> <i>NOTCH3</i> <i>NTRK3</i> Exons 16, 17 <i>PAX5</i> <i>PIK3C2B</i> <i>POLD1</i> <i>PRKCI</i> <i>RAD21</i> <i>Exons</i> 3, 4, 6, 7, 10, 14, 15, 17 <i>RNF43</i> <i>SETD2</i>	NPM1 Exons 4-6, 8, 10 P2RY8 PBRM1 PIK3C2G POLE PTCH1 RAD51 RARA ROS1 Exons 31, 36-38, 40 SF3B1	NRAS Exons 2, 3 PALB2 PDCD1 (PD-1) PIK3CA Exons 2, 3, 5-8, 10, 14,1 9, 21 (Coding Exons 1, 2, 4-7, 9, 13, 18, 20) PPARG PTEN RAD51B RB1 RB1 RPTOR SGK1	NSD3 (WHSCILI) PARK2 PDCDILG2 (PD-L2) PIK3CB PPP2R1A PTPN11 RAD5IC RBM10 SDHA SMAD2
TYR03 U2AF1 VEGFA VHL WHSC1 WT1 XP01	NKX2-1 NT5C2 PARP1 PDGFRA Exons 12, 18 PIK3R1 PPP2R2A PTPRO RAD51D REL SDHB SMAD4	MYD88 Exon 4 NOTCH1 NTRK1 Exons 14, 15 PARP2 PDGFRB Exons 12-21, 23 PIM1 PRDM1 QK1 RAD52 RET Exons 11, 13-16 SDHC SMARCA4	NBN NOTCH2 NTRK2 PARP3 PDK1 PMS2 PRKAR1A RAC1 RAD54L RICTOR SDHD SMARCB1	43-45, 47, 48, 53, 56 <i>NF1</i> <i>NOTCH3</i> <i>NTRK3</i> Exons 16, 17 <i>PAX5</i> <i>PIK3C2B</i> <i>POLD1</i> <i>PRKCI</i> <i>RAD21</i> <i>Exons</i> 3, 4, 6, 7, 10, 14, 15, 17 <i>RNF43</i> <i>SETD2</i> <i>SMO</i>	NPM1 Exons 4-6, 8, 10 P2RY8 PBRM1 PIK3C2G POLE PTCH1 RAD51 RARA ROS1 Exons 31, 36-38, 40 SF3B1 SNCAIP	NRAS Exons 2, 3 PALB2 PDCD1 (PD-1) PIK3CA Exons 2, 3, 5-8, 10, 14,1 9, 21 (Coding Exons 1, 2, 4-7, 9, 15, 18, 20) PPARG PTEN RAD51B RB1 RPTOR SGK1 SOCS1	NSD3 (WHSCILI) PARK2 PDCDILG2 (PD-L2) PIK3CB PPP2RIA PTPN11 RAD5IC RBM10 SDHA SMAD2 SOX2
	NKX2-1 NT5C2 PARP1 PDGFRA Exons 12, 18 PIK3R1 PPP2R2A PTPRO RAD51D REL SDHB SMAD4 SOX9	MYD88 Exon 4 NOTCH1 NTRK1 Exons 14, 15 PARP2 PDGFR8 Exons 12-21, 23 PIM1 PRDM1 QK1 RAD52 RET Exons 11, 13-16 SDHC SMARCA4 SPEN	NBN NOTCH2 NTRK2 PARP3 PDK1 PMS2 PRKAR1A RAC1 RAD54L RICTOR SDHD SMARCB1 SPOP	43-45, 47, 48, 53, 56 NF1 NOTCH3 NTRK3 Exons 16, 17 PAX5 PIK3C2B POLD1 PRKCI RAD21 Exons 3, 4, 6, 7, 10, 14, 15, 17 RNF43 SETD2 SMO SRC	NPM1 Exons 4-6, 8, 10 P2RY8 PBRM1 PIK3C2G POLE PTCH1 RAD51 RARA RO51 Exons 31, 36-38, 40 SF3B1 SNCAIP STAG2 TERC*	NRAS Exons 2, 3 PALB2 PDCDI (PD-1) PIK3CA Exons 2, 3, 5-8, 10, 14,1 9, 21 (Coding Exons 1, 2, 4-7, 9, 13, 18, 20) PPARG PTEN RAD51B RB1 RPTOR SGK1 SOCS1 STAT3 TERT*	NSD3 (WHSCILI) PARK2 PDCDILG2 (PD-L2) PIK3CB PPP2RIA PTPN11 RAD5IC RBM10 SDHA SMAD2 SOX2 SOX2 STK11
XRCC2 ZNF217 ZNF703	NKX2-1 NT5C2 PARP1 PDGFRA Exons 12, 18 PIK3R1 PPP2R2A PTPRO RAD51D REL SDHB SMAD4 SOX9 SUFU	MYD88 Exon 4 NOTCH1 NTRK1 Exons 14, 15 PARP2 PDGFRB Exons 12-21, 23 PIM1 PRDM1 QK1 RAD52 RET Exons 11, 13-16 SDHC SMARCA4 SPEN SYK	NBN NOTCH2 NTRK2 PARP3 PDK1 PMS2 PRKARIA RAC1 RAD54L RICTOR SDHD SMARCB1 SPOP TBX3	43-45, 47, 48, 53, 56 <i>NF1</i> <i>NOTCH3</i> <i>NTRK3</i> Exons 16, 17 <i>PAX5</i> <i>PIK3C2B</i> <i>POLD1</i> <i>PRKC1</i> <i>RAD21</i> <i>RAF1</i> Exons 3, 4, 6, 7, 10, 14, 15, 17 <i>RNF43</i> <i>SETD2</i> <i>SMO</i> <i>SRC</i> <i>TEK</i>	NPM1 Exons 4-6, 8, 10 P2RY8 PBRM1 PIK3C2G POLE PTCH1 RAD51 RARA RARA ROS1 Exons 31, 36-38, 40 SF3B1 SNCAIP STAG2 TERC* ncRNA	NRAS Exons 2, 3 PALB2 PDCDI (PD-1) PIK3CA Exons 2, 3, 5-8, 10, 14, 1 9, 21 (Coding Exons 1, 2, 4-7, 9, 13, 18, 20) PPARG PTEN RAD51B RB1 RPTOR SGK1 SOCS1 SOCS1 STAT3 FERT* Promoter	NSD3 (WHSCILI) PARK2 PDCD1LG2 (PD-L2) PIK3CB PPP2RIA PTPN11 RAD5IC RBM10 SDHA SMAD2 SOX2 SOX2 STK11 TET2
	NKX2-1 NT5C2 PARP1 PDGFRA Exons 12, 18 PIK3R1 PPP2R2A PTPRO RAD51D REL SDHB SMAD4 SOX9 SUFU TGFBR2	MYD88 Exon 4 NOTCH1 NTRK1 Exons 14, 15 PARP2 PDGFRB Exons 12-21, 23 PIM1 PRDM1 QK1 RAD52 RET Exons 11, 13-16 SDHC SMARCA4 SPEN SYK TIPARP	NBN NOTCH2 NTRK2 PARP3 PDK1 PMS2 PRKAR1A RAC1 RAD54L RICTOR SDHD SMARCB1 SPOP TBX3 TNFAIP3	43-45, 47, 48, 53, 56 <i>NF1</i> <i>NOTCH3</i> <i>NTRK3</i> Exons 16, 17 <i>PAX5</i> <i>PIK3C2B</i> <i>POLD1</i> <i>PRKC1</i> <i>RAD21</i> <i>RAF1</i> <i>Exons 3</i> , 4, 6, 7, 10, 14, 15, 17 <i>RNF43</i> <i>SETD2</i> <i>SMO</i> <i>SRC</i> <i>TEK</i> <i>TNFRSF14</i>	NPM1 Exons 4-6, 8, 10 P2RY8 PBRM1 PIK3C2G POLE PTCH1 RAD51 RARA RARA RO51 Exons 31, 36-38, 40 SF3B1 SNCAIP STAG2 TAG2 TERC* ncRNA	NRAS Exons 2, 3 PALB2 PDCDI (PD-1) PIK3CA Exons 2, 3, 5-8, 10, 14, 1 9, 21 (Coding Exons 1, 2, 4-7, 9, 13, 18, 20) PARG PARG PAEN RAD51B RB1 SGK1 SOCS1 STAT3 FERT* Promoter TSC1	NSD3 (WHSCILI) PARK2 PDCD1LG2 (PD-L2) PIK3CB PPP2RIA PTPN11 RAD5IC RBM10 SDHA SDHA SMAD2 SOX2 STK11 TET2 TSC2



Summary of Analytical Sensitivity and Specificity for Professional Services Content

Results from our Limit of Detection (LoD) study are shown below, indicating the median variant allele frequency, tumor fraction or unstable loci at which the test has shown 95% probability of detection.² Please refer to our product labeling for a list of the 75 genes baited for enhanced sensitivity and complete product specifications.

ALTERATION TYPE	MEDIAN LIMIT OF DETECTION (LOD)
MSI	0.8% Unstable loci
bTMB (component indels)	1.00% VAF*
bTMB (component subs)	1.00% VAF*

VAF = variant allele frequency; TF = tumor fraction

* The accuracy of %VAF / %TF have not been analytically validated

In our Limit of Blank study, which evaluated variant calling in healthy donors, 1,735 unique variants were included in the analysis for a total of 137,065 data points. A total of 18 false positives were observed across 4 unique short variants. The LoB was determined to be the ideal value of zero for short variants, rearrangements and CNAs. The false positive rate was shown to be 0% for rearrangements and CNAs and 0.013% (-1 in 8,000) for short variants (substitutions and indels).²



Information Provided as a Professional Service

As a professional service, FoundationOne Liquid CDx interrogates 324 genes, including 309 genes with complete exonic (coding) coverage and 15 genes with only select non-coding coverage (indicated with an *); **75 genes (indicated in bold) are captured with increased sensitivity** and have complete exonic (coding) coverage unless otherwise noted. The test also detects tumor fraction and the genomic signatures blood mutational burden (bTMB) and microsatellite instability high (MSI-H) status.

ABL1 Exons 4-9	ACVR1B	AKT1 Exon 3	AKT2	AKT3	ALK Exons 20-29, Introns 18, 19	ALOX12B
AMER1 (FAM123B)	APC	AR	ARAF Exons 4, 5, 7, 11, 13, 15, 16	ARFRP1	ARID1A	ASXL1
ATM	ATR	ATRX	AURKA	AURKB	AXIN1	AXL
BAP1	BARD1	BCL2	BCL2L1	BCL2L2	BCL6	BCOR
BCORL1	<i>BCR*</i> Introns 8, 13, 14	BRAF Exons 11-18, Introns 7-10	BRCA1 Introns 2, 7, 8, 12, 16, 19, 20	BRCA2 Intron 2	BRD4	BRIP1
BTG1	BTG2	BTK Exons 2, 15	C11orf30 (EMSY)	C17orf39 (GID4)	CALR	CARD11
CASP8	CBFB	CBL	CCND1	CCND2	CCND3	CCNE1
CD22	CD70	CD74* Introns 6-8	CD79A	CD79B	CD274 (PD-L1)	CDC73
CDH1	CDK12	CDK4	CDK6	CDK8	CDKN1A	CDKN1B
CDKN2A	CDKN2B	CDKN2C	CEBPA	CHEK1	CHEK2	CIC
CREBBP	CRKL	CSF1R	CSF3R	CTCF	CTNNA1	CTNNB1 Exon 3
CUL3	CUL4A	CXCR	CYP17A1	DAXX	DDR1	<i>DDR2</i> Exons 5, 17, 18
DIS3	DNMT3A	DOT1L	EED	EGFR Introns 7, 15, 24-27	EP300	EPHA3
EPHB1	EPHB4	ERBB2	<i>ERBB3</i> Exons 3, 6, 7, 8, 10, 12, 20, 21, 23, 24, 25	ERBB4	ERCC4	ERG
ERRFI1	ESR1 Exons 4-8	ETV4* Intron 8	<i>ETV5*</i> Introns 6, 7	<i>ETV6*</i> Introns 5, 6	EWSR1* Introns 7-13	<i>EZH2</i> Exons 4, 16, 17, 18
EZR* Introns 9-11	FAM46C	FANCA	FANCC	FANCG	FANCL	FAS
FBXW7	FGF10	FGF12	FGF14	FGF19	FGF23	FGF3
FGF4	FGF6	FGFR1 Introns 1, 5, Intron 17	FGFR2 Intron 1, Intron 17	FGFR3 Exons 7, 9 (alternative designation exon 10), 14, 18, Intron 17	FGFR4	FH
FLCN	FLT1	<i>FLT3</i> Exons 14, 15, 20	FOXL2	FUBP1	GABRA6	GATA3
GATA4	GATA6	GNA11 Exons 4, 5	GNA13	GNAQ Exons 4, 5	GNAS Exons 1, 8	GRM3
GSK3B	H3F3A	HDAC1	HGF	HNF1A	HRAS Exons 2, 3	HSD3B1
ID3	<i>IDH1</i> Exon 4	IDH2 Exon 4	IGF1R	IKBKE	IKZF1	INPP4B
IRF2	IRF4	IRS2	JAK1	JAK2 Exon 14	<i>JAK3</i> Exons 5, 11, 12, 13, 15, 16	JUN
KDM5A	KDM5C	KDM6A	KDR	KEAP1	KEL	KIT Exons 8, 9, 11, 12, 13, 17, Intron 16
KLHL6	KMT2A (MLL) Introns 6, 8-11, Intron 7	KMT2D (MLL2)	KRAS	LTK	LYN	MAF

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(Information Provided as a Professional Service Continued)

MAP2K1 (MEK1) Exons 2, 3	MAP2K2 (MEK2) Exons 2-4, 6, 7	MAP2K4	MAP3K1	MAP3K13	MAPK1	MCL1
MDM2	MDM4	MED12	MEF2B	MEN1	MERTK	MET
MITF	MKNKI	MLH1	MPL Exon 10	MRE11A	MSH2 Intron 5	MSH3
MSH6	MSTIR	ΜΤΑΡ	<i>MTOR</i> Exons 19, 30, 39, 40, 43-45, 47, 48, 53, 56	MUTYHMYB* Intron 14	MYC Intron 1	
MYCL (MYCL1)	MYCN	MYD88 Exon 4	NBN	NF1	NF2	NFE2L2
NFKBIA	NKX2-1	NOTCH1	NOTCH2 Intron 26	NOTCH3	<i>NPM1</i> Exons 4-6, 8, 10	NRAS Exons 2, 3
NSD3 (WHSC1L1)	NT5C2	NTRK1 Exons 14, 15, Introns 8-11	NTRK2 Intron 12	NTRK3 Exons 16, 17	NUTM1* Intron 1	P2RY8
PALB2	PARK2	PARP1	PARP2	PARP3	PAX5	PBRM1
PDCD1 (PD-1)	PDCD1LG2 (PD-L2)	PDGFRA Exons 12, 18, Introns 7, 9, 11	PDGFRB Exons 12-21, 23	PDK1	PIK3C2B	PIK3C2G
<i>PIK3CA</i> Exons 2, 3, 5-8, 10, 14, 19, 21 (Coding Exons 1, 2, 4-7, 9, 13, 18, 20)	PIK3CB	PIK3R1	PIM1	PMS2	POLDI	POLE
PPARG	PPP2R1A	PPP2R2A	PRDM1	PRKAR1A	PRKCI	PTCH1
PTEN	PTPN11	PTPRO	QKI	RAC1	RAD21	RAD51
RAD51B	RAD51C	RAD51D	RAD52	RAD54L	RAF1 Exons 3, 4, 6, 7, 10, 14, 15, 17, Introns 4-8	RARA Intron 2
RB1	RBM10	REL	RET Introns 7, 8, Exons 11, 13-16, Introns 9-11	RICTOR	RNF43	ROS1 Exons 31, 36-38, 40, Introns 31-35
RPTOR	RSPO2* Intron 1	SDC4* Intron 2	SDHA	SDHB	SDHC	SDHD
SETD2	SF3B1	SGK1	SLC34A2* Intron 4	SMAD2	SMAD4	SMARCA4
SMARCB1	SMO	SNCAIP	SOCS1	SOX2	SOX9	SPEN
SPOP	SRC	STAG2	STAT3	STK11	SUFU	SYK
TBX3	TEK	TERC* ncRNA	<i>TERT</i> * Promoter	TET2	TGFBR2	TIPARP
TMPRSS2* Introns 1-3	TNFAIP3	TNFRSF14	TP53	TSC1	TSC2	TYRO3
U2AF1	VEGFA	VHL	WHSC1	WT1	XPO1	XRCC2
ZNF217	ZNF703					
		VHL	WHSC1	WT1	XPO1	

‡ Current as of July 2021. Please visit foundationmedicine.com for the most up-to-date gene list.

FoundationOne*CDx and FoundationOne*Liquid CDx are qualitative next-generation sequencing based in vitro diagnostic tests for advanced cancer patients with solid tumors and are for prescription use only. FoundationOne CDx utilizes FFPE tissue and analyzes 324 genes as well as genomic signatures. FoundationOne Liquid CDx analyzes 324 genes utilizing circulating cell-free DNA and is FDA-approved to report short variants in 311 genes. The tests are companion diagnostics to identify patients who may benefit from treatment with specific therapies in accordance with the 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 tests 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 testing with FoundationOne CDx when archival tissue is not available which may pose a risk. Patients who are tested with FoundationOne Liquid CDx and are negative for companion diagnostic mutations should be reflexed to tumor tissue testing information, please visit www.FICDxLabel.com and www.FILCDxLabel.com.

References:

1. FoundationOne Liquid CDx Technical Information. For full label refer to www.F1LCDxLabel.com

2. Data on File, Foundation Medicine, Inc., 2020



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