Technical Specifications

FOUNDATIONONE CDx™

Intended Use

FoundationOne CDx™ (F1CDx) is a next generation sequencing based *in vitro* diagnostic device for detection of substitutions, insertion and deletion alterations (indels), and copy number alterations (CNAs) in 324 genes and select gene rearrangements, as well as genomic signatures including microsatellite instability (MSI) and tumor mutational burden (TMB) using DNA isolated from formalin-fixed paraffin embedded (FFPE) tumor tissue specimens. The test is intended 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. Additionally, F1CDx 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. The F1CDx assay is a single-site assay performed at Foundation Medicine, Inc.

Table 1: Companion diagnostic indications

INDICATIONS	BIOMARKER	FDA-APPROVED THERAPY*
Non-Small Cell Lung Cancer (NSCLC)	*EGFR* exon 19 deletions and *EGFR* exon 21 L858R alterations	Gilotrif® (afatinib), Iressa® (gefitinib), or Tarceva® (erlotinib)
	EGFR exon 20 T790M alterations	Tagrisso® (osimertinib)
	ALK rearrangements	Alecensa® (alectinib), Xalkori® (crizotinib), or Zykadia® (ceritinib)
	BRAF V600E	Tafinlar® (dabrafenib) in combination with Mekinist® (trametinib)
Melanoma	*BRAF* V600E	Tafinlar® (dabrafenib) or Zelboraf® (vemurafenib)
	BRAF V600E or V600K	Mekinist® (trametinib) or Cotellic® (cobimetinib), in combination with Zelboraf® (vemurafenib)
Breast Cancer	*ERBB2* (HER2) amplification	Herceptin® (trastuzumab), Kadcyla® (ado-trastuzumab-emtansine), or Perjeta® (pertuzumab)
Colorectal Cancer	*KRAS* wild-type (absence of mutations in codons 12 and 13)	Erbitux® (cetuximab)
	KRAS wild-type (absence of mutations in exons 2, 3 and 4) and *NRAS* wild-type (absence of mutations in exons 2, 3 and 4)	Vectibix® (panitumumab)
Ovarian Cancer	*BRCA1/2* alterations	Rubraca® (rucaparib)

* Tarceva® is the registered trademark of OSI Pharmaceuticals, LLC. Zelboraf®, Herceptin®, Perjeta®, Kadcyla®, and Cotellic® are registered trademarks of Genentech, Inc. Gilotrif® is a registered trademark of Boehringer Ingelheim International GmbH. Iressa® and Tagrisso® are registered trademarks of the AstraZeneca group of companies. Xalkori® is a registered trademark of Pfizer Inc. Zykadia®, Tafinlar®, and Mekinist® are registered trademarks of Novartis AG Corporation Switzerland. Erbitux® is a registered trademark of ImClone LLC, a wholly owned subsidiary of Eli Lilly and Company. Alecensa® is a registered trademark of Chugai Seiyaku Kabushiki Kaisha. Vectibix® is a registered trademark of Immunex Corporation. Rubraca® is a registered trademark of Clovis Oncology, Inc.

Summary of Clinical Studies

Follow-on CDx claims were based on a non-inferiority statistical testing approach using the enrichment design presented in the paper by Li (2016).[1] All studies passed the acceptance criteria specific in each study protocol.

BIOMARKER	POSITIVE PERCENT AGREEMENT (PPA)†	NEGATIVE PERCENT AGREEMENT (NPA)	COMPARATOR METHOD*
EGFR Exon 19 Deletions and L858R	98.1% (106/108)	99.4% (153/154)	cobas® *EGFR* Mutation Test v2
EGFR T790M	98.9% (87/88)	86.1% (93/108)	cobas® *EGFR* Mutation Test v1 cobas® *EGFR* Mutation Test v2
ALK Rearrangements	92.9% (78/84)	100% (75/75)	Ventana *ALK* (D5F3) CDx Assay Vysis *ALK* Break-Apart FISH Probe Kit
KRAS	100% (173/173)	100% (154/154)	therascreen® *KRAS* RGQ PCR Kit
ERBB2 (HER2) Amplifications	89.4% (101/113)	98.4% (180/183)	Dako HER2 FISH PharmDx® Kit
BRAF V600	99.4% (166/167)	89.6% (121/135)‡	cobas® *BRAF* V600 Mutation Test
BRAF V600E	99.3% (149/150)	99.2% (121/122)	
BRAF V600 dinucleotide§	96.3% (26/27)	100% (24/24)	THxID® *BRAF* kit

* Cobas® is a trademark of Roche Diagnostics Operations, Inc. Therascreen® is a trademark of Qiagen. PharmDx® is a registered trademark of Dako Denmark A/S. THxID® is a registered trademark of bioMérieux.
† The reference standard used to calculate PPA and NPA is defined as the consensus calls between the two comparator methods – PPA being when FoundationOne CDx and the comparator method(s) identified mutations in mutated patients and NPA being when FoundationOne CDx and the comparator method(s) did not identify mutations in non-mutated patients.
‡ Sensitivity of dinucleotide detection of *BRAF* V600K and V600E was found to be significantly reduced in cobas® test, in particular for samples in which FoundationOne CDx detected the dinucleotides to be of lower than 40% mutant allele frequency (MAF), leading to low NPA values.
§ A study using the THxID® BRAF kit (bioMérieux) was conducted with samples with BRAF V600 dinucleotide mutation detected by F1CDx and BRAF V600 negative samples to provide a better evaluation of V600 dinucleotide concordance.

FOUNDATION MEDICINE®

www.foundationmedicine.com | Tel. 888.988.3639 | Fax 617.418.2290 | MKT-0092-02

Current Gene List[2]

Genes with full coding exonic regions included in FoundationOne CDx for the detection of substitutions, insertion-deletions (indels), and copy-number alterations (CNAs).

ABL1	*ACVR1B*	*AKT1*	*AKT2*	*AKT3*	*ALK*	*ALOX12B*	*AMER1 (FAM123B)*	*APC*
AR	*ARAF*	*ARFRP1*	*ARID1A*	*ASXL1*	*ATM*	*ATR*	*ATRX*	*AURKA*
AURKB	*AXIN1*	*AXL*	*BAP1*	*BARD1*	*BCL2*	*BCL2L1*	*BCL2L2*	*BCL6*
BCOR	*BCORL1*	*BRAF*	*BRCA1*	*BRCA2*	*BRD4*	*BRIP1*	*BTG1*	*BTG2*
BTK	*C11orf30 (EMSY)*	*CALR*	*CARD11*	*CASP8*	*CBFB*	*CBL*	*CCND1*	*CCND2*
CCND3	*CCNE1*	*CD22*	*CD274 (PD-L1)*	*CD70*	*CD79A*	*CD79B*	*CDC73*	*CDH1*
CDK12	*CDK4*	*CDK6*	*CDK8*	*CDKN1A*	*CDKN1B*	*CDKN2A*	*CDKN2B*	*CDKN2C*
CEBPA	*CHEK1*	*CHEK2*	*CIC*	*CREBBP*	*CRKL*	*CSF1R*	*CSF3R*	*CTCF*
CTNNA1	*CTNNB1*	*CUL3*	*CUL4A*	*CXCR4*	*CYP17A1*	*DAXX*	*DDR1*	*DDR2*
DIS3	*DNMT3A*	*DOT1L*	*EED*	*EGFR*	*EP300*	*EPHA3*	*EPHB1*	*EPHB4*
ERBB2	*ERBB3*	*ERBB4*	*ERCC4*	*ERG*	*ERRFI1*	*ESR1*	*EZH2*	*FAM46C*
FANCA	*FANCC*	*FANCG*	*FANCL*	*FAS*	*FBXW7*	*FGF10*	*FGF12*	*FGF14*
FGF19	*FGF23*	*FGF3*	*FGF4*	*FGF6*	*FGFR1*	*FGFR2*	*FGFR3*	*FGFR4*
FH	*FLCN*	*FLT1*	*FLT3*	*FOXL2*	*FUBP1*	*GABRA6*	*GATA3*	*GATA4*
GATA6	*GID4 (C17orf39)*	*GNA11*	*GNA13*	*GNAQ*	*GNAS*	*GRM3*	*GSK3B*	*H3F3A*
HDAC1	*HGF*	*HNF1A*	*HRAS*	*HSD3B1*	*ID3*	*IDH1*	*IDH2*	*IGF1R*
IKBKE	*IKZF1*	*INPP4B*	*IRF2*	*IRF4*	*IRS2*	*JAK1*	*JAK2*	*JAK3*
JUN	*KDM5A*	*KDM5C*	*KDM6A*	*KDR*	*KEAP1*	*KEL*	*KIT*	*KLHL6*
KMT2A (MLL)	*KMT2D (MLL2)*	*KRAS*	*LTK*	*LYN*	*MAF*	*MAP2K1 (MEK1)*	*MAP2K2 (MEK2)*	*MAP2K4*
MAP3K1	*MAP3K13*	*MAPK1*	*MCL1*	*MDM2*	*MDM4*	*MED12*	*MEF2B*	*MEN1*
MERTK	*MET*	*MITF*	*MKNK1*	*MLH1*	*MPL*	*MRE11A*	*MSH2*	*MSH3*
MSH6	*MST1R*	*MTAP*	*MTOR*	*MUTYH*	*MYC*	*MYCL (MYCL1)*	*MYCN*	*MYD88*
NBN	*NF1*	*NF2*	*NFE2L2*	*NFKBIA*	*NKX2-1*	*NOTCH1*	*NOTCH2*	*NOTCH3*
NPM1	*NRAS*	*NT5C2*	*NTRK1*	*NTRK2*	*NTRK3*	*P2RY8*	*PALB2*	*PARK2*
PARP1	*PARP2*	*PARP3*	*PAX5*	*PBRM1*	*PDCD1 (PD-1)*	*PDCD1LG2 (PD-L2)*		*PDGFRA*
PDGFRB	*PDK1*	*PIK3C2B*	*PIK3C2G*	*PIK3CA*	*PIK3CB*	*PIK3R1*	*PIM1*	*PMS2*
POLD1	*POLE*	*PPARG*	*PPP2R1A*	*PPP2R2A*	*PRDM1*	*PRKAR1A*	*PRKCI*	*PTCH1*
PTEN	*PTPN11*	*PTPRO*	*QKI*	*RAC1*	*RAD21*	*RAD51*	*RAD51B*	*RAD51C*
RAD51D	*RAD52*	*RAD54L*	*RAF1*	*RARA*	*RB1*	*RBM10*	*REL*	*RET*
RICTOR	*RNF43*	*ROS1*	*RPTOR*	*SDHA*	*SDHB*	*SDHC*	*SDHD*	*SETD2*
SF3B1	*SGK1*	*SMAD2*	*SMAD4*	*SMARCA4*	*SMARCB1*	*SMO*	*SNCAIP*	*SOCS1*
SOX2	*SOX9*	*SPEN*	*SPOP*	*SRC*	*STAG2*	*STAT3*	*STK11*	*SUFU*
SYK	*TBX3*	*TEK*	*TET2*	*TGFBR2*	*TIPARP*	*TNFAIP3*	*TNFRSF14*	*TP53*
TSC1	*TSC2*	*TYRO3*	*U2AF1*	*VEGFA*	*VHL*	*WHSC1 (MMSET)*	*WHSC1L1*	*WT1*
XPO1	*XRCC2*	*ZNF217*	*ZNF703*					

Select Rearrangements[2,3]

Genes with select intronic regions for the detection of gene rearrangements, one gene with a promoter region and one non-coding RNA gene.

ALK	*BCL2*	*BCR*	*BRAF*	*BRCA1*	*BRCA2*	*CD74*	*EGFR*	*ETV4*
ETV5	*ETV6*	*EWSR1*	*EZR*	*FGFR1*	*FGFR2*	*FGFR3*	*KIT*	*KMT2A (MLL)*
MSH2	*MYB*	*MYC*	*NOTCH2*	*NTRK1*	*NTRK2*	*NUTM1*	*PDGFRA*	*RAF1*
RARA	*RET*	*ROS1*	*RSPO2*	*SDC4*	*SLC34A2*	*TERC**	*TERT (promoter only)***	
TMPRSS2								

**TERC* is non-coding RNA gene. ***TERT* is gene with promoter region.

FoundationOne CDx™ is a next-generation sequencing based *in vitro* diagnostic device for detection of substitutions, insertion and deletion alterations, and copy number alterations in 324 genes and select gene rearrangements, as well as genomic signatures including microsatellite instability (MSI) and tumor mutational burden (TMB) using DNA isolated from formalin-fixed, paraffin-embedded (FFPE) tumor tissue specimens. For the complete intended use statement, including companion diagnostic indications and warnings and limitations, please see the FoundationOne CDx Technical Information, *www.foundationmedicine.com/f1cdx*.

Reference

1. Li M. Statistical Methods for Clinical Validation of Follow-On Companion Diagnostic Devices via an External Concordance Study. Statistics in Biopharmaceutical Research 8, 355-363 (2016).
2. Current as of December 12, 2017. Please visit www.*foundationmedicine.com/f1cdx* for the most up-to-date gene list.
3. Refer to our full label for listing of intronic regions at *www.foundationmedicine.com/f1cdx*.

FOUNDATION MEDICINE®

www.foundationmedicine.com | Tel. 888.988.3639 | Fax 617.418.2290 | MKT-0092-02

Technical Specifications

FOUNDATIONONE®HEME

FoundationOneHeme is a comprehensive genomic profiling assay for hematologic malignancies and sarcomas.

Methods[1]

- Uses hybrid-capture next-generation sequencing.
- Identifies the four classes of genomic alterations (base substitutions, insertions and deletions, copy number alterations, and rearrangements).
- Sequences DNA of the entire coding region of 406 genes and selected introns of 31 genes involved in rearrangements.
- Sequences RNA of 265 genes commonly rearranged in cancer to better identify known and novel gene fusions.
- Sequences to a median depth of ~500X unique coverage for DNA and RNA to an average of ~6.9 million unique pairs.
- All specimen are reviewed by a hematopathologist or pathologist to ensure specimen viability and tumor content.

PERFORMANCE SPECIFICATIONS		
Sensitivity	Base Substitutions at ≥5% Minor Allele Frequency	>99%
	Insertions/Deletions (1-40 base pairs) at ≥10% Minor Allele Frequency	98%
	Focal Copy Number Alterations (homozygous deletions or amplifications ≥8 copies)	>95%
	Known Gene Fusions	>95%
Specificity (PPV)	Positive Predictive Value (PPV) for Base Substitutions, Insertions/Deletions and Focal Copy Number Alterations	>99%
	Positive Predictive Value (PPV) for Known Gene Fusions	>95%
Reproducibility	Concordance between replicates inter-batch	97%
	Concordance between replicates intra-batch	97%
Immunotherapy Biomarkers	TMB† and MSI‡	
Specimen Type	Peripheral whole blood, bone marrow aspirate, FFPE block or slides, or extracted nucleic acid (see Specimen Instructions for more details)	
Turnaround Time	2 Weeks§	

† Chalmers ZR, et. al. "Analysis of 100,000 human cancer genomes reveals the landscape of tumor mutational burden". Genome Med. 2017;9(1):34.
‡ Hall MJ, et al. Multigene Panels to Evaluate Hereditary Cancer Risk: Reckless or Relevant? J Clin Oncol. 2016 Dec;34(34):4186-4187."
§ Based on typical turnaround time from receipt of sample

Reporting

- Test results are provided in an interpretive report, curated by biomedical informatics scientists, and approved by on-site board-certified and licensed pathologists and hematopathologists.
- Genomic findings are listed with clinically relevant targeted therapies, immunotherapies, and clinical trials.
- Reported alterations may indicate response or lack of response to validated targets for therapy (approved or in clinical trials), or may be unambiguous drivers of oncogenesis based on reported scientific knowledge.
- Reports include tumor mutational burden (TMB) status and microsatellite instability (MSI) status, biomarkers that may help predict response to checkpoint inhibitors.
- Test results are available via our online portal at www.foundationmedicine.com* or by fax.

*Visit *foundationmedicine.com* to create an online account.

FOUNDATION MEDICINE®

www.foundationmedicine.com | Tel. 888.988.3639 | Fax 617.418.2290 | MKT-0057-03

Current Gene List[2]

Entire coding sequence (base substitutions, indels, copy number alterations)

ABL1 *ACTB* *AKT1* *AKT2* *AKT3* *ALK* *AMER1 (FAM123B or WTX)* *APC*
APH1A *AR* *ARAF* *ARFRP1* *ARHGAP26 (GRAF)* *ARID1A* *ARID2* *ASMTL* *ASXL1*
ATM *ATR* *ATRX* *AURKA* *AURKB* *AXIN1* *AXL* *B2M* *BAP1*
BARD1 *BCL10* *BCL11B* *BCL2* *BCL2L2* *BCL6* *BCL7A* *BCOR* *BCORL1*
BIRC3 *BLM* *BRAF* *BRCA1* *BRCA2* *BRD4* *BRIP1 (BACH1)* *BRSK1* *BTG2*
BTK *BTLA* *C11orf30 (EMSY)* *CAD* *CALR* *CARD11* *CBFB* *CBL* *CCND1*
CCND2 *CCND3* *CCNE1* *CCT6B* *CD22* *CD274 (PD-L1)* *CD36* *CD58* *CD70*
CD79A *CD79B* *CDC73* *CDH1* *CDK12* *CDK4* *CDK6* *CDK8* *CDKN1B*
CDKN2A *CDKN2B* *CDKN2C* *CEBPA* *CHD2* *CHEK1* *CHEK2* *CIC* *CIITA*
CKS1B *CPS1* *CREBBP* *CRKL* *CRLF2* *CSF1R* *CSF3R* *CTCF* *CTNNA1*
CTNNB1 *CUX1* *CXCR4* *DAXX* *DDR2* *DDX3X* *DNM2* *DNMT3A* *DOT1L*
DTX1 *DUSP2* *DUSP9* *EBF1* *ECT2L* *EED* *EGFR* *ELP2* *EP300*
EPHA3 *EPHA5* *EPHA7* *EPHB1* *ERBB2* *ERBB3* *ERBB4* *ERG* *ESR1*
ETS1 *ETV6* *EXOSC6* *EZH2* *FAF1* *FAM46C* *FANCA* *FANCC* *FANCD2*
FANCE *FANCF* *FANCG* *FANCL* *FAS (TNFRSF6)* *FBXO11* *FBXO31* *FBXW7* *FGF10*
FGF14 *FGF19* *FGF23* *FGF3* *FGF4* *FGF6* *FGFR1* *FGFR2* *FGFR3*
FGFR4 *FHIT* *FLCN* *FLT1* *FLT3* *FLT4* *FLYWCH1* *FOXL2* *FOXO1*
FOXO3 *FOXP1* *FRS2* *GADD45B* *GATA1* *GATA2* *GATA3* *GID4 (C17orf39)* *GNA11*
GNA12 *GNA13* *GNAQ* *GNAS* *GPR124* *GRIN2A* *GSK3B* *GTSE1* *HDAC1*
HDAC4 *HDAC7* *HGF* *HIST1H1C* *HIST1H1D* *HIST1H1E* *HIST1H2AC* *HIST1H2AG* *HIST1H2AL*
HIST1H2AM *HIST1H2BC* *HIST1H2BJ* *HIST1H2BK* *HIST1H2BO* *HIST1H3B* *HNF1A* *HRAS* *HSP90AA1*
ICK *ID3* *IDH1* *IDH2* *IGF1R* *IKBKE* *IKZF1* *IKZF2* *IKZF3*
IL7R *INHBA* *INPP4B* *INPP5D (SHIP)* *IRF1* *IRF4* *IRF8* *IRS2* *JAK1*
JAK2 *JAK3* *JARID2* *JUN* *KAT6A (MYST3)* *KDM2B* *KDM4C* *KDM5A* *KDM5C*
KDM6A *KDR* *KEAP1* *KIT* *KLHL6* *KMT2A (MLL)* *KMT2C (MLL3)* *KMT2D (MLL2)* *KRAS*
LEF1 *LRP1B* *LRRK2* *MAF* *MAFB* *MAGED1* *MALT1* *MAP2K1 (MEK1)* *MAP2K2 (MEK2)*
MAP2K4 *MAP3K1* *MAP3K14* *MAP3K6* *MAP3K7* *MAPK1* *MCL1* *MDM2* *MDM4*
MED12 *MEF2B* *MEF2C* *MEN1* *MET* *MIB1* *MITF* *MKI67* *MLH1*
MPL *MRE11A* *MSH2* *MSH3* *MSH6* *MTOR* *MUTYH* *MYC* *MYCL (MYCL1)*
MYCN *MYD88* *MYO18A* *NCOR2* *NCSTN* *NF1* *NF2* *NFE2L2* *NFKBIA*
NKX2-1 *NOD1* *NOTCH1* *NOTCH2* *NPM1* *NRAS* *NT5C2* *NTRK1* *NTRK2*
NTRK3 *NUP93* *NUP98* *P2RY8* *PAG1* *PAK3* *PALB2* *PASK* *PAX5*
PBRM1 *PC* *PCBP1* *PCLO* *PDCD1 (PD-1)* *PDCD11* *PDCD1LG2 (PD-L2)* *PDGFRA* *PDGFRB*
PDK1 *PHF6* *PIK3CA* *PIK3CG* *PIK3R1* *PIK3R2* *PIM1* *PLCG2* *POT1*
PPP2R1A *PRDM1* *PRKAR1A* *PRKDC* *PRSS8* *PTCH1* *PTEN* *PTPN11* *PTPN2*
PTPN6 (SHP-1) *PTPRO* *RAD21* *RAD50* *RAD51* *RAF1* *RARA* *RASGEF1A* *RB1*
RELN *RET* *RHOA* *RICTOR* *RNF43* *ROS1* *RPTOR* *RUNX1* *S1PR2*
SDHA *SDHB* *SDHC* *SDHD* *SERP2* *SETBP1* *SETD2* *SF3B1* *SGK1*
SMAD2 *SMAD4* *SMARCA1* *SMARCA4* *SMARCB1* *SMC1A* *SMC3* *SMO* *SOCS1*
SOCS2 *SOCS3* *SOX10* *SOX2* *SPEN* *SPOP* *SRC* *SRSF2* *STAG2*
STAT3 *STAT4* *STAT5A* *STAT5B* *STAT6* *STK11* *SUFU* *SUZ12* *TAF1*
TBL1XR1 *TCF3 (E2A)* *TCL1A (TCL1)* *TET2* *TGFBR2* *TLL2* *TMEM30A* *TMSB4XP8 (TMSL3)*
TNFAIP3 *TNFRSF11A* *TNFRSF14* *TNFRSF17* *TOP1* *TP53* *TP63* *TRAF2* *TRAF3*
TRAF5 *TSC1* *TSC2* *TSHR* *TUSC3* *TYK2* *U2AF1* *U2AF2* *VHL*
WDR90 *WHSC1 (MMSET or NSD2)* *WISP3* *WT1* *XBP1* *XPO1* *YY1AP1* *ZMYM3*
ZNF217 *ZNF24 (ZSCAN3)* *ZNF703* *ZRSR2*

Select DNA Rearrangements[3]

ALK *BCL2* *BCL6* *BCR* *BRAF* *CCND1* *CRLF2* *EGFR* *EPOR*
ETV1 *ETV4* *ETV5* *ETV6* *EWSR1* *FGFR2* *IGH* *IGK* *IGL*
JAK1 *JAK2* *KMT2A (MLL)* *MYC* *NTRK1* *PDGFRA* *PDGFRB* *RAF1* *RARA*
RET *ROS1* *TMPRSS2* *TRG*

FOUNDATION MEDICINE®

www.foundationmedicine.com | Tel. 888.988.3639 | Fax 617.418.2290 | MKT-0057-03

Select RNA Gene Fusions

ABI1	*ABL1*	*ABL2*	*ACSL6*	*AFF1*	*AFF4*	*ALK*	*ARHGAP26 (GRAF)*
ARHGEF12	*ARID1A*	*ARNT*	*ASXL1*	*ATF1*	*ATG5*	*ATIC*	*BCL10*
BCL11A	*BCL11B*	*BCL2*	*BCL3*	*BCL6*	*BCL7A*	*BCL9*	*BCOR*
BCR	*BIRC3*	*BRAF*	*BTG1*	*CAMTA1*	*CARS*	*CBFA2T3*	*CBFB*
CBL	*CCND1*	*CCND2*	*CCND3*	*CD274 (PD-L1)*	*CDK6*	*CDX2*	*CHIC2*
CHN1	*CIC*	*CIITA*	*CLP1*	*CLTC*	*CLTCL1*	*CNTRL (CEP110)*	*COL1A1*
CREB3L1	*CREB3L2*	*CREBBP*	*CRLF2*	*CSF1*	*CTNNB1*	*DDIT3*	*DDX10*
DDX6	*DEK*	*DUSP22*	*EGFR*	*EIF4A2*	*ELF4*	*ELL*	*ELN*
EML4	*EP300*	*EPOR*	*EPS15*	*ERBB2*	*ERG*	*ETS1*	*ETV1*
ETV4	*ETV5*	*ETV6*	*EWSR1*	*FCGR2B*	*FCRL4*	*FEV*	*FGFR1*
FGFR1OP	*FGFR2*	*FGFR3*	*FLI1*	*FNBP1*	*FOXO1*	*FOXO3*	*FOXO4*
FOXP1	*FSTL3*	*FUS*	*GAS7*	*GLI1*	*GMPS*	*GPHN*	*HERPUD1*
HEY1	*HIP1*	*HIST1H4I*	*HLF*	*HMGA1*	*HMGA2*	*HOXA11*	*HOXA13*
HOXA3	*HOXA9*	*HOXC11*	*HOXC13*	*HOXD11*	*HOXD13*	*HSP90AA1*	*HSP90AB1*
IGH	*IGK*	*IGL*	*IKZF1*	*IL21R*	*IL3*	*IRF4*	*ITK*
JAK1	*JAK2*	*JAK3*	*JAZF1*	*KAT6A (MYST3)*	*KDSR*	*KIF5B*	*KMT2A (MLL)*
LASP1	*LCP1*	*LMO1*	*LMO2*	*LPP*	*LYL1*	*MAF*	*MAFB*
MALT1	*MDS2*	*MECOM*	*MKL1*	*MLF1*	*MLLT1 (ENL)*	*MLLT10 (AF10)*	*MLLT3*
MLLT4 (AF6)	*MLLT6*	*MN1*	*MNX1*	*MSI2*	*MSN*	*MUC1*	*MYB*
MYC	*MYH11*	*MYH9*	*NACA*	*NBEAP1 (BCL8)*	*NCOA2*	*NDRG1*	*NF1*
NF2	*NFKB2*	*NIN*	*NOTCH1*	*NPM1*	*NR4A3*	*NSD1*	*NTRK1*
NTRK2	*NTRK3*	*NUMA1*	*NUP214*	*NUP98*	*NUTM2A*	*OMD*	*P2RY8*
PAFAH1B2	*PAX3*	*PAX5*	*PAX7*	*PBX1*	*PCM1*	*PCSK7*	*PDCD1LG2 (PD-L2)*
PDE4DIP	*PDGFB*	*PDGFRA*	*PDGFRB*	*PER1*	*PHF1*	*PICALM*	*PIM1*
PLAG1	*PML*	*POU2AF1*	*PPP1CB*	*PRDM1*	*PRDM16*	*PRRX1*	*PSIP1*
PTCH1	*PTK7*	*RABEP1*	*RAF1*	*RALGDS*	*RAP1GDS1*	*RARA*	*RBM15*
RET	*RHOH*	*RNF213*	*ROS1*	*RPL22*	*RPN1*	*RUNX1*	*RUNX1T1 (ETO)*
RUNX2	*SEC31A*	*SEPT5*	*SEPT6*	*SEPT9*	*SET*	*SH3GL1*	*SLC1A2*
SNX29 (RUNDC2A)	*SRSF3*	*SS18*	*SSX1*	*SSX2*	*SSX4*	*STAT6*	*STL*
SYK	*TAF15*	*TAL1*	*TAL2*	*TBL1XR1*	*TCF3 (E2A)*	*TCL1A (TCL1)*	*TEC*
TET1	*TFE3*	*TFG*	*TFPT*	*TFRC*	*TLX1*	*TLX3*	*TMPRSS2*
TNFRSF11A	*TOP1*	*TP63*	*TPM3*	*TPM4*	*TRIM24*	*TRIP11*	*TTL*
TYK2	*USP6*	*WHSC1 (MMSET or NSD2)*	*WHSC1L1*	*YPEL5*	*ZBTB16*	*ZMYM2*	*ZNF384*
ZNF521							

To learn more about our scientific and analytical validation see our publication in Blood[1] : “Integrated genomic DNA/RNA profiling of hematologic malignancies in the clinical setting.”

References

1. He, J. et al. (2016) Integrated genomic DNA/RNA profiling of hematologic malignancies in the clinical setting. Blood. 127(24):3004-14.
2. Current as of November 2017. Please visit www.foundationmedicine.com for the most up-to-date gene list.
3. Select Introns only. Detailed list available upon request.

FOUNDATION MEDICINE®

www.foundationmedicine.com | Tel. 888.988.3639 | Fax 617.418.2290 | MKT-0057-03