xF+ Validation

xF+ is an non-invasive liquid biopsy assay intended for the detection of cell-free DNA (cfDNA) in blood specimens from patients with advanced solid tumors.

The assay covers clinically relevant exons and select non-coding regions in 523 genes. The assay aims to identify substitutions (single nucleotide variants [SNVs] and multi-nucleotide variants [MNVs]), insertion and deletion alterations (INDELs), copy number gains (CNGs) as listed in the xF+ Gene Panel. Enhanced coverage is applied to 114 genes, allowing for a lower limit of detection (0.2% VAF for SNVs). Select variants may be reported at VAFs lower than 0.2% at pathologist discretion.* The assay also reports on Blood Tumor Mutational Burden (bTMB) and Microsatellite Instability High (MSI-H) status when detected. Tempus xF+ is designed to help capture clinically relevant biomarkers for solid tumors.

CAP/CLIA validation of the Tempus xF+ panel at Tempus' Chicago, Illinois laboratory focused on the detection of actionable oncologic variants including resistance mutations in plasma. The assay requires two 8.5 mL Streck tubes of peripheral blood. Clinical sequencing is performed to >5000x and >1500x unique coverage for enhanced and non-enhanced regions, respectively. Performance specifications are listed in the table below. These results establish high sensitivity and specificity for the Tempus xF+ assay.

Not intended for:

- Hematologic malignancies
- Early stage (stage I/II) cancers
- Primary CNS malignancies

xF+ PERFORMANCE SPECIFICATIONS

Variant Class	VAF	Sensitivity	Specificity	LOD
SNVs (Enhanced)	≥0.2%	98.3%	>99.9%	0.2%
SNVs (Non-Enhanced)	≥1%	>99.9%	>99.9%	1%
INDELs (Enhanced)	≥0.25%	95.5%	>99.9%	0.25%
INDELs (Non-Enhanced)	≥2%	87.5%	>99.9%	2%
CNGs	≥1%	>99.9%	93.0%	1%
Rearrangements	≥1%	96.8%	>99.9%	1%
MSI-H Status	—	90.0%	>99.9%	—
bTMB**	—	63.6%	98.3%	—

* *Sensitivity of detecting variants with VAFs lower than 0.2% may be lower than listed.*

** *bTMB has a reporting threshold of ≥0.25% ctDNA Tumor Fraction.*

xF+ Gene List

ABCC3 [2]	*BIRC3* [2]	*CREBBP* [2]	*ERBB4* [2]	*FLT1* [2]	*ID3* [2]	***KRAS*** [1]	*MYB* [2]	*PHLPP2* [2]	***RAD51C*** [1]	*SMARCB1* [2]	***TSC1*** [1]
ABL1 [1]	*BLM* [2]	***CRKL*** [1]	*ERCC2* [2]	***FLT3*** [1]	***IDH1*** [1]	*LATS1* [2]	***MYC*** [1,4]	*PIAS4* [2]	*RAD51D* [2]	*SMC1A* [2]	***TSC2*** [1]
ABL2 [2]	*BMPR1A* [2]	*CSF1R* [2]	*ERCC3* [2]	*FLT4* [2]	***IDH2*** [1]	*LCK* [2]	*MYCL* [2]	*PIK3C2B* [2]	*RAD52* [2]	*SMC3* [2]	*TSHR* [2]
ABRAXAS1 [2]	***BRAF*** [1,3]	*CSF3R* [2]	*ERCC4* [2]	*FOLH1* [2]	*IFNA21* [2]	*LMO1* [2]	***MYCN*** [1]	*PIK3C2G* [2]	*RAD54L* [2]	***SMO*** [1]	*TYMS* [2]
ACVR1 [2]	***BRCA1*** [1]	*CTC1* [2]	*ERCC6* [2]	*FOXA1* [2]	*IFNAR1* [2]	*LRP1B* [2]	***MYD88*** [1]	***PIK3CA*** [1]	***RAF1*** [1]	*SNCAIP* [2]	*TYRO3* [2]
ACVR1B [2]	***BRCA2*** [1]	*CTCF* [2]	*ERG* [2]	***FOXL2*** [1]	*IFNAR2* [2]	*LTK* [2]	*NBN* [2]	*PIK3CB* [2]	*RARA* [2]	*SOCS1* [2]	*U2AF1* [2]
AJUBA [2]	*BRD4* [2]	*CTLA4* [2]	***ERRFI1*** [1]	*FOXO1* [2]	*IFNG* [2]	*LYN* [2]	*NCOA2* [2]	*PIK3CD* [2]	*RASA1* [2]	*SOS1* [2]	*UGT1A1* [2]
AKT1 [1]	*BRIP1* [2]	*CTNNA1* [2]	***ESR1*** [1]	*FOXO3* [2]	*IFNGR1* [2]	*LZTR1* [2]	*NCOR1* [2]	*PIK3CG* [2]	***RB1*** [1]	*SOX2* [2]	***VEGFA*** [1]
AKT2 [1]	*BTG1* [2]	***CTNNB1*** [1]	*ETNK1* [2]	*FOXP1* [2]	*IFNGR2* [2]	*MAF* [2]	***NF1*** [1]	***PIK3R1*** [1]	*RBM10* [2]	*SOX9* [2]	***VHL*** [1]
AKT3 [2]	*BTG2* [2]	*CUL3* [2]	*ETV1* [2]	*FRS2* [2]	*IFNW1* [2]	*MALT1* [2]	***NF2*** [1]	*PIK3R2* [2]	*RECQL4* [2]	*SPEN* [2]	*VSIR* [2]
ALK [1,3]	***BTK*** [1]	*CUL4A* [2]	*ETV4* [2]	*FUBP1* [2]	*IGF1* [2]	***MAP2K1*** [1]	***NFE2L2*** [1]	*PIM1* [2]	*REL* [2]	***SPOP*** [1]	*WEE1* [2]
ALOX12B [2]	*CALR* [2]	*CUX1* [2]	*ETV5* [2]	*GABRA6* [2]	*IGF1R* [2]	***MAP2K2*** [1]	*NFKBIA* [2]	*PLCG1* [2]	***RET*** [1,3]	*SRC* [2]	*WNK1* [2]
AMER1 [2]	*CARD11* [2]	*CXCR4* [2]	*ETV6* [2]	*GALNT12* [2]	*IKBKE* [2]	*MAP2K4* [2]	*NKX2-1* [2]	*PLCG2* [2]	***RHEB*** [1]	*SRSF2* [2]	*WRN* [2]
APC [1]	*CARM1* [2]	*CYLD* [2]	*EWSR1* [2]	*GATA1* [2]	*IKZF1* [2]	*MAP3K1* [2]	***NOTCH1*** [1]	*PMS1* [2]	***RHOA*** [1]	*STAG2* [2]	*WT1* [2]
APLNR [2]	*CASP8* [2]	*CYP17A1* [2]	***EZH2*** [1]	***GATA3*** [1]	*IL10RA* [2]	*MAP3K13* [2]	*NOTCH2* [2]	***PMS2*** [1]	*RICTOR* [2]	*STAT3* [2]	*XBP1* [2]
AR [1]	*CBFB* [2]	*CYSLTR2* [2]	*EZR* [2]	*GATA4* [2]	*IL32* [2]	*MAP3K21* [2]	*NOTCH3* [2]	*POLA1* [2]	***RIT1*** [1]	*STAT5B* [2]	*XPA* [2]
ARAF [1]	*CBL* [2]	*DAXX* [2]	*FAM46C* [2]	*GATA6* [2]	*IL6R* [2]	*MAP3K7* [2]	*NOTCH4* [2]	*POLD1* [2]	***RNF43*** [1]	*STAT6* [2]	*XPC* [2]
ARFRP1 [2]	***CCND1*** [1]	*DDB2* [2]	*FANCA* [2]	*GID4* [2]	*IL7R* [2]	***MAPK1*** [1]	***NPM1*** [1]	*POLE* [2]	***ROS1*** [1,3]	***STK11*** [1]	*XPO1* [2]
ARID1A [1]	***CCND2*** [1]	*DDR1* [2]	*FANCC* [2]	*GLI2* [2]	*IMPDH1* [2]	***MAPK3*** [1]	*NQO1* [2]	*POLQ* [2]	*RPS6KB1* [2]	*SUFU* [2]	*XRCC1* [2]
ARID1B [2]	***CCND3*** [1]	***DDR2*** [1]	*FANCD2* [2]	***GNA11*** [1]	*ING1* [2]	*MAX* [2]	***NRAS*** [1]	*POT1* [2]	*RPTOR* [2]	*SUZ12* [2]	*XRCC2* [2]
ARID2 [2]	***CCNE1*** [1,4]	*DDX3X* [2]	*FANCE* [2]	*GNA13* [2]	*INPP4B* [2]	*MC1R* [2]	*NRG1* [2]	*PPARG* [2]	*RRM1* [2]	*SYK* [2]	*YEATS4* [2]
ASNS [2]	*CD22* [2]	*DDX41* [2]	*FANCG* [2]	***GNAQ*** [1]	*INSR* [2]	*MCL1* [2]	*NSD1* [2]	*PPM1D* [2]	*RSF1* [2]	*TBX3* [2]	*ZFHX3* [2]
ASXL1 [2]	***CD274****(PD-L1)* [1,4]	*DEPTOR* [2]	*FANCI* [2]	***GNAS*** [1]	*IRF1* [2]	***MDM2*** [1,4]	*NSD2* [2]	*PPP2R1A* [2]	*RSPO2* [2]	*TCF7L2* [2]	*ZMYM3* [2]
ATM [1]	*CD70* [2]	*DICER1* [2]	*FANCL* [2]	*GPC3* [2]	*IRF2* [2]	*MDM4* [2]	*NSD3* [2]	*PPP2R2A* [2]	*RUNX1* [2]	*TEK* [2]	*ZNF217* [2]
ATR [1]	*CD74* [2]	*DIS3* [2]	*FANCM* [2]	*GPS2* [2]	*IRF4* [2]	*MED12* [2]	*NT5C2* [2]	*PPP6C* [2]	*RXRA* [2]	*TERC* [2]	*ZNF703* [2]
ATRX [2]	*CD79A* [2]	*DNMT1* [2]	*FAS* [2]	*GREM1* [2]	*IRS2* [2]	*MEF2B* [2]	***NTRK1*** [1,3]	*PRDM1* [2]	*SDC4* [2]	***TERT*** [1]	*ZNF750* [2]
AURKA [2]	*CD79B* [2]	*DNMT3A* [2]	*FAT1* [2]	*GRIN2A* [2]	***JAK1*** [1]	*MEN1* [2]	***NTRK2*** [1,3]	*PREX2* [2]	***SDHA*** [1]	*TET2* [2]	*ZNRF3* [2]
AURKB [2]	*CDC73* [2]	*DOT1L* [2]	***FBXW7*** [1]	*GRM3* [2]	***JAK2*** [1]	*MERTK* [2]	***NTRK3*** [1,3]	*PRKACA* [2]	*SDHAF2* [2]	*TFEB* [2]	*ZRSR2* [2]
AURKC [2]	***CDH1*** [1]	*DPYD* [2]	*FCGR2A* [2]	*GSK3B* [2]	***JAK3*** [1]	***MET*** [1,4]	*NUTM1* [2]	*PRKAR1A* [2]	*SDHB* [2]	*TGFB1* [2]	
AXIN1 [2]	***CDK12*** [1]	*EBF1* [2]	*FCGR3A* [2]	*GSTP1* [2]	*JUN* [2]	*MITF* [2]	*P2RY8* [2]	*PRKCI* [2]	*SDHC* [2]	*TGFBR1* [2]	
AXIN2 [2]	***CDK4*** [1]	*EED* [2]	*FGF10* [2]	*H3F3A* [2]	*KAT6A* [2]	*MKNK1* [2]	*PAK1* [2]	*PRKN* [2]	*SDHD* [2]	*TGFBR2* [2]	
AXL [2]	***CDK6*** [1]	*EEF2* [2]	*FGF12* [2]	*HAVCR2* [2]	*KDM5A* [2]	***MLH1*** [1]	***PALB2*** [1]	***PTCH1*** [1]	*SETBP1* [2]	*TIGIT* [2]	
B2M [1]	*CDK8* [2]	***EGFR*** [1,4]	*FGF14* [2]	*HDAC1* [2]	*KDM5C* [2]	*MLH3* [2]	*PALLD* [2]	***PTEN*** [1]	*SETD2* [2]	*TIPARP* [2]	
BAP1 [1]	*CDK9* [2]	*EGLN1* [2]	*FGF19* [2]	*HDAC2* [2]	*KDM5D* [2]	***MPL*** [1]	*PARP1* [2]	*PTK2* [2]	*SF3B1* [2]	*TMEM127* [2]	
BARD1 [2]	*CDKN1A* [2]	*EIF1AX* [2]	*FGF23* [2]	*HGF* [2]	*KDM6A* [2]	*MRE11* [2]	*PARP2* [2]	***PTPN11*** [1]	*SGK1* [2]	*TMPRSS2* [2]	
BAX [2]	*CDKN1B* [2]	*ELF3* [2]	*FGF3* [2]	*HIF1A* [2]	***KDR*** [1]	*MS4A1* [2]	*PARP3* [2]	*PTPN13* [2]	*SIRPA* [2]	*TNFAIP3* [2]	
BCL2 [2]	***CDKN2A*** [1]	*EMSY* [2]	*FGF4* [2]	*HIST1H3B* [2]	***KEAP1*** [1]	***MSH2*** [1]	*PAX5* [2]	*PTPRD* [2]	*SLC34A2* [2]	*TNFRSF14* [2]	
BCL2L1 [2]	*CDKN2B* [2]	*EP300* [2]	*FGF6* [2]	*HLA-B* [5]	*KEL* [2]	***MSH3*** [1]	***PBRM1*** [1]	*PTPRO* [2]	*SLC9A3R1* [2]	*TNFRSF17* [2]	
BCL2L11 [2]	*CDKN2C* [2]	*EPCAM* [2]	***FGFR1*** [1,3]	***HNF1A*** [1]	***KIT*** [1]	***MSH6*** [1]	*PDCD1* [2]	*PTPRT* [2]	*SLFN11* [2]	*TOP1* [2]	
BCL2L2 [2]	*CEBPA* [2]	*EPHA2* [2]	***FGFR2*** [1,3]	*HNF1B* [2]	*KLF4* [2]	*MST1R* [2]	***PDCD1LG2*** [1]	*QKI* [2]	*SLIT2* [2]	*TOP2A* [2]	
BCL6 [2]	*CHD4* [2]	*EPHA3* [2]	***FGFR3*** [1,3]	*HOXB13* [2]	*KLHL6* [2]	*MTAP* [2]	***PDGFRA*** [1]	*RAC1* [2]	*SMAD2* [2]	***TP53*** [1]	
BCLAF1 [2]	*CHEK1* [2]	*EPHB1* [2]	***FGFR4*** [1]	***HRAS*** [1]	*KLLN* [2]	*MTHFR* [2]	***PDGFRB*** [1]	*RAD21* [2]	*SMAD3* [2]	*TP53BP1* [2]	
BCOR [2]	***CHEK2*** [1]	*EPHB4* [2]	*FH* [2]	*HSD3B1* [2]	***KMT2A*** [1]	***MTOR*** [1]	*PDK1* [2]	*RAD50* [2]	***SMAD4*** [1]	*TP63* [2]	
BCORL1 [2]	*CIC* [2]	***ERBB2****(HER2)* [1,4]	*FHIT* [2]	*HSP90AA1* [2]	*KMT2C* [2]	*MUC16* [2]	*PHGDH* [2]	*RAD51* [2]	*SMARCA2* [2]	*TRAF3* [2]	
BCR [2]	*CKS1B* [2]	***ERBB3*** [1]	*FLCN* [2]	*HSPH1* [2]	*KMT2D* [2]	*MUTYH* [2]	*PHLPP1* [2]	*RAD51B* [2]	*SMARCA4* [2]	*TRAF7* [2]	

GENE REARRANGEMENTS

ALK, BRAF, FGFR1, FGFR2, FGFR3, NTRK1, NTRK2, NTRK3, RET, ROS1

COPY NUMBER GAINS

CCNE1, CD274(PD-L1), EGFR, ERBB2(HER2), MDM2, MET, MYC

1 *Enhanced SNV/Indel* 2 *Non-Enhanced SNV/Indel* 3 *Rearrangement* 4 *CNG* 5 *Variants not reported*