ASSAY SPECIFICATIONS

Therapy Selection

TISSUE-FREE LIQUID BIOPSY FOR LATE-STAGE SOLID TUMORS

NORTHSTAR SELECT

ABOUT THE ASSAY

Northstar Select® is an ultra-sensitive comprehensive genomic profiling (CGP) assay for therapy selection, intended for use in late-stage, solid tumor cancers. Maximize opportunities for treatment by evaluating 84 guideline-recommended genes for SNV / indels (82), copy number alterations (CNA); amplifications (19) *and* losses (5), fusions (9) and MSI-H status, all with a non-invasive, circulating tumor DNA (ctDNA) blood test.

PERFORMANCE CHARACTERISTICS[a]

Variant Type	LOD at 95% Confidence[b]	Specificity	Reportable Range
SNVs	0.15% VAF	>99.9999%	≥0.01%
Indels			
CNA[c]	2.11 copies (amplification) 1.80 copies (loss)	>99.9%	≥2.10 copies (amplification) ≤1.90 copies (loss)
Fusion	0.30% tumor fraction	>99.9%	≥0.02%
MSI-H[d]	0.07% tumor fraction	>99.9%	n/a

a. Internal data on file, Aug 2025
b. LOD95: the lowest concentration of an analyte in a sample that can be consistently detected with ≥95% probability
c. 2.5% tumor fraction at 6 copies of amplification.
d. Microsatellite instability-high, impacted by biological variability.

SPECIMEN REQUIREMENTS & PROCESSING

Sample Collection

3* x 10 mL tubes

Streck cfDNA BCT blood tubes filled to the top (≥8 mL)

* minimum 2 tubes

Mobile phlebotomy available by request

Storage & Shipping

Room temperature

Do not freeze or refrigerate

Ordering

Provider portal

Online convenience: portal.northstaronc.com

Turnaround Time

7-10 days or less

From sample receipt to results

Northstar Select is covered by Medicare.

> Qualified beneficiaries have $0 out-of-pocket costs.*

BillionToOne is committed to making their tests accessible to all and have created the *Northstar Financial Assistance Program* to support and advocate for each patient depending on their individual needs.

* Northstar Select has obtained Medicare for eligible beneficiaries with advanced solid tumors who meet the coverage criteria outlined in the local coverage determination

GENES by Alteration Type

SNVs / Indels 82 genes

AKT1	*CCNE1*	*EZH2*	*JAK2*	*NOTCH1*	*RB1*
AKT2	*CD274* (PD-L1)	*FANCA*	*JAK3*	*NPM1*	*RET*
ALK	*CDH1*	*FBXW7*	*KIT*	*NRAS*	*RHOA*
APC	*CDK12*	*FGFR1*	*KRAS*	*NTRK1*	*RIT1*
AR	*CDK4*	*FGFR2*	*MAP2K1* (MEK1)	*PALB2*	*ROS1*
ARAF	*CDK6*	*FGFR3*	*MAP2K2* (MEK2)	*PDGFRA*	*SF3B1*
ARID1A	*CDKN2A*	*FGFR4*	*MET*	*PIK3CA*	*SMAD4*
ATM	*CDKN2B*	*GATA3*	*MLH1*	*PMS2*	*SMO*
BRAF	*CHEK2*	*GNA11*	*MPL*	*PTEN*	*STK11*
BRCA1	*CTNNB1*	*GNAQ*	*MSH2*	*PTPN11*	*TERT*
BRCA2	*DDR2*	*GNAS*	*MSH6*	*RAD51C*	*TP53*
BRIP1	*EGFR*	*HRAS*	*MTOR*	*RAD51D*	*TSC1*
CCND1	*ERBB2* (HER2)	*IDH1*	*MYC*	*RAF1*	*VHL*
CCND2	*ESR1*	*IDH2*	*NF1*		

CNAs: Amplifications 19 genes

AR	*ERBB2*	*MYC*
BRAF	*ESR1*	*PDGFRA*
CCNE1	*FGFR1*	*PIK3CA*
CD274 (PD-L1)	*FGFR2*	*RAF1*
CDK4	*KIT*	*RET*
CDK6	*KRAS*	
EGFR	*MET*	

CNAs: Losses 5 genes

ATM	*CDKN2A*
BRCA1	*PTEN*
BRCA2	

Fusions 9 genes

ALK
BRAF
FGFR2
FGFR3
NTRK1
NTRK2
NTRK3
RET
ROS1

Biomarker

MSI-H

GENES by Most Common Solid Tumor Types as Recommended by Guidelines

Breast

AKT1	*ESR1*	*PALB2*
BRCA1	*FGFR1*	*PIK3CA*
BRCA2	*FGFR2*	*PTEN*
ERBB2	*FGFR3*	

Colorectal

BRAF	*NRAS*
ERBB2	MSI-H
KRAS	

Lung

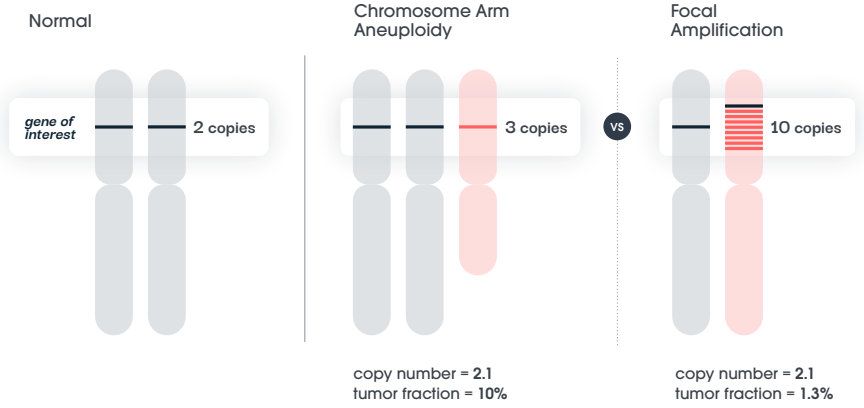
ALK	*FGFR1*	*KRAS*
BRAF	*FGFR2*	*MET*
EGFR	*FGFR3*	*RET*
ERBB2	*FGFR4*	*ROS1*

All Solid Tumors

BRAF	*NTRK1*	*RET*
ERBB2	*NTRK2*	MSI-H
	NTRK3	

About Copy Number Alterations (CNAs)

Northstar Select is the only CGP that differentiates between **"driver" focal amplifications** from broad aneuploidies that exhibit **"passenger" copy number differences**.



With **~90% of solid tumors** found to harbor chromosome instability that can lead to aneuploidy, differentiation from focal amplification is critical as aneuploidies currently lack specific targeted therapies and are often associated with resistance.

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