

This liquid biopsy test can provide insight into what therapies may be appropriate for a patient with a stage III or IV solid tumor cancer. It can be used to help inform first-line therapy selection or during disease progression to inform alternative treatments. It is not appropriate for hematologic malignancies.

Includes 81 genes for single nucleotide variants (SNVs) / indels, 24 genes for copy-number alterations (CNAs), and 8 genes for fusions using next generation sequencing (NGS). The genomic coverage includes genes relevant to selection of FDA-approved targeted and immuno-oncology therapies as well as those genes relevant to early phase drug development efforts:

PERFORMANCE SPECIFICATIONS

BillionToOne's proprietary technology enables circulating tumor DNA molecule counting down to a single molecule level. Combined with ultra-high capture efficiency and unique bioinformatics analysis, Northstar Select™ can detect SNVs / indels and fusions down to two mutated molecules (0.02-0.04% allele fraction equivalent at the average DNA inputs (15-30ng) level) in the specimen. The following table shows the analytical performance of the assay:

Alteration Type	Reportable Range	Allele Fraction / Copy Number	Analytical Sensitivity	Analytical Specificity
SNVs / Indels	≥0.02%	>0.25% 0.14 - 0.22% 0.05 - 0.13%	99.1% 97.5% 83.3%	>99.9%
CNAs: Amplifications	≥2.15 copies	2.15 - 2.30 copies >2.30 copies	94.9% 100%	
Fusions	≥0.02%	—	>99%	

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