GUARDANT360® Assay Specifications

Test. Take Action.

ABOUT GUARDANT360®

Guardant360 provides guideline-recommended genomic results including high microsatellite instability (MSI-High) in 7 days from sample receipt at the laboratory using a routine blood draw, eliminating the need to solely rely on tissue testing. Guardant360 enables informed treatment decisions for advanced solid-tumor cancer patients and identifies treatment options or clinical trials for patients before first-line therapy or at progression.

USING GUARDANT360 IN CLINICAL PRACTICE

Indicated for:

- Advanced solid-tumor cancers
- Before first-line therapy or at progression

Not indicated for:

- Hematologic malignancies
- Early stage cancers
- When disease is stable or responding to therapy

TEST SPECIFICATIONS

Sample type and volume
Two 10 mL tubes of whole blood.

Storage and shipping conditions
Ship same or next day at room temperature. Do not freeze or refrigerate.

Test turnaround time
7 calendar days from sample receipt at the laboratory to results.

PERFORMANCE SPECIFICATIONS

Alteration Type	Reportable Range	Allelic Fraction/ Copy Number	Analytical Sensitivity	Analytical Specificity*
SNVs	≥0.04%	>0.25%	100%	100%
		0.05 - 0.25%	77%	98%
Indels	≥0.04%	>0.5%	100%	100%
		0.1 - 0.5%	74%	
Fusions**	≥0.04%	≥0.3%	100%	100%
		<0.3%	91%	
CNAs***	≥2.18 copies	2.3 copies	100%	100%
MSI	Detected/ Not Detected	≥0.1%	95%	100%

Based on cell-free DNA input of 30 ng in patient samples. Analytical sensitivity cited above are for targeted, clinically important regions. Sensitivity outside these regions or in highly repetitive sequence contexts may vary.

*Over entire genomic reportable range of Guardant360 panel.

**Based on fusion detection in ALK, NTRK1, RET, ROS1

***Based on ERBB2 (HER2) and MET analytical sensitivity. Copy number sensitivity may vary with other genes

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GUARDANT™