Guardant360® Provides More Information for Progressing Patients with Advanced Solid Tumors Not Responding to Therapy

COVERED BY MEDICARE ACROSS ADVANCED CANCERS*

GUARDANT360 ENABLES YOU TO PROFILE YOUR PATIENT'S TUMOR AND FIND NEW POTENTIAL THERAPY OPTIONS

BIOMARKERS RECOMMENDED IN GUIDELINES ACROSS ALL SOLID TUMORS

There are FDA-approved therapies available for patients with *NTRK* fusions, MSI-High status, or select TMB scores

BLADDER
- *FGFR3* fusions and other alterations ◆

BREAST
- *PIK3CA* mutations ◆
- *ERBB2* (HER2) amplification ◆
- *BRCA1/2* germline# and somatic ◆
- *ESR1* mutations

CHOLANGIOCARCINOMA
- *IDH1* mutations

COLORECTAL
- MSI-High ◆
- Extended *KRAS* mutations
- Extended *NRAS* mutations
- *BRAF* V600E ◆
- *ERBB2* (HER2) amplification
- *EGFR* mutations

ENDOMETRIAL
- MSI-High ◆
- *ERBB2* (HER2) amplification

GASTRIC/GASTROESOPHAGEAL
- *ERBB2* (HER2) amplification ◆

GIST
- *KIT* mutations ◆
- *PDGFRA* mutations ◆
- *BRAF* mutations
- *FGFR3* fusions

MELANOMA
- *BRAF* V600E/K ◆
- *KIT* mutations
- *NRAS* mutations
- *ALK* fusions
- *ROS1* fusions

LUNG
- *EGFR* exon 19 del, L858R and other alterations ◆
- *ALK* fusions ◆
- *ROS1* fusions ◆
- *BRAF* V600E ◆
- *MET* exon 14 skipping ◆
- *RET* fusions ◆
- *ERBB2* exon 20 insertions and other alterations
- *MET* amplifications
- *KRAS* mutations

OVARIAN
- *BRCA1/2* germline# and somatic ◆

PANCREATIC
- *BRCA1/2* germline# and somatic ◆

PROSTATE
- *BRCA1/2* germline# and somatic ◆
- *ATM* mutations ◆
- Expanded HRR genes ◆

THYROID
- *RET* fusions ◆
- *BRAF* V600E (anaplastic)
- *ALK* fusions (anaplastic)

#Guardant360 is neither intended nor validated for the reporting or interpretation of germline variants and recommend verification with an assay validated for germline testing. FDA indications are limited to germline variants (except for prostate)

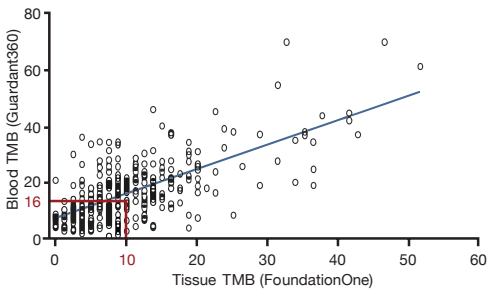
◆ Associated FDA-approved matched therapy

TEST FOR ALL GENOMIC BIOMARKERS, INCLUDING BLOOD TMB, EXPANDED HRR, AND *NTRK1-3*

- The number of personalized therapy options for advanced cancer patients continues to grow, giving patients who may have cycled through standard of care therapies additional options.
- Guardant360 covers guideline-recommended biomarkers, including tumor mutational burden (TMB), MSI-High, expanded HRR gene set, and full coverage of *NTRK* fusions.
- Ensures progressing patients are given the opportunity to be eligible for these new treatment options, without the need to obtain archival tissue or subject the patient to another invasive biopsy.
- A simple blood draw provides results in only 10 days#.

FAST AND RELIABLE TMB TESTING WITH GUARDANT360

- Checkpoint inhibition has been FDA-approved for patients who have no satisfactory alternative treatment option with a tissue TMB score of 10 mut/Mb or higher.
- Using Guardant360 for TMB assessment is easy - only two tubes of blood are needed to assess TMB across nearly 500 genes, leading to a highly accurate assessment of the TMB biomarker.



Study background[1]: A large, clinical study (n=809 patients) of blood TMB in patients with newly diagnosed NSCLC using Guardant360 compared to tissue TMB.

Study results: Subset analysis (n=352 patients) found that a Guardant360 TMB score of 16 mut/Mb correlates with a tissue TMB score of 10 mut/Mb.

*Excludes patients with central nervous system tumors | #Sample receipt to result

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GUARDANT360®

Find More Patients with Prostate Cancer who may be Eligible for PARP Inhibitor Therapy by Testing for Expanded HRR Genes

COVERED BY MEDICARE ACROSS ADVANCED CANCERS*

TEST FOR *BRCA1, BRCA2, ATM*, AND THE EXPANDED HRR GENE SET† WITH GUARDANT360

- Expanded HRR gene testing provides patients the opportunity to be eligible for PARP inhibitor therapy.
- In addition to *BRCA1* and *BRCA2* mutations, there are additional HRR genes that are FDA-approved to show benefit from PARP inhibition.

PATIENTS WITH METASTATIC CASTRATION-RESISTANT PROSTATE CANCER (MCRPC) WITH *BRCA1, BRCA2, ATM*, OR THE EXPANDED HRR GENE SET MUTATIONS† BENEFIT FROM PARP INHIBITOR THERAPY[2]

A recent pivotal study in men with mCRPC who had disease progression while receiving a new hormonal agent and had an HRR gene mutation found the following benefit from a select PARP inhibitor therapy:

- PFS was over 2x longer for patients with *BRCA1, BRCA2,* or *ATM* mutations treated with a PARP inhibitor compared to standard of care.
- Patients with an alteration in the expanded HRR gene set† had a 1.65x benefit compared to standard of care.

†Expanded HRR gene set includes *ATM, BRCA1, BRCA2, CDK12, CHEK2, FANCA, PALB2, RAD51D*

GUARDANT360 PERFORMANCE SPECIFICATIONS

Guardant360 identifies 80+ clinically relevant genes and biomarkers, including TMB, MSI-High, expanded HRR, and full coverage of the *NTRK* genes.

Alteration Type	Reportable Range	Allelic Fraction /Copy Number	Analytical Sensitivity	Analytical Specificity^
SNVs	≥ 0.06%	0.5-100%	100%	100%
		0.1-0.5%	86.0%	99.5%
Indels	≥ 0.04%	0.5-100%	99.7%	100%
		0.1-0.5%	70.6%	
Fusions	≥ 0.06%	0.3-100%	100%	100%
		0.05-0.3%	87.0%	
CNAs	≥ 2.12 copies	>2.3 copies	99.3%	100%
MSI	MSI-H detected	>0.1	95.0%	100%

Performance based on cell-free DNA input of 30 ng in patient or contrived samples. Analytical sensitivity cited above are for targeted, clinically important regions. Sensitivity outside the regions or in highly repetitive sequence contexts may vary. ^Over entire genomic reportable range of Guardant360 panel.

REFERENCES: 1. Rizvi, N.A., et al. *JAMA Oncology,* 2020 2. de Bono, D.B., et al. *New England Journal of Medicine,* 2020

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