







REPORTING	PHYSICIAN	 <i>Complete Tumor Response Map on page 2</i>
Report Date: NOV-15-2022	Chih-Hsueh Chen	
Receipt Date: NOV-09-2022	Account: Genconn Biotech Co., LTD	
Collection Date: NOV-08-2022	Address: F15., No 207-5 Sec 3, Beixin Rd, Xindian	
Specimen: Blood	Dist, New Taipei City, 23143, Taiwan	
Status: FINAL	Ph: +886 963 820 633   Fax: N/A	
	Additional Recipient: N/A	

Summary of Detected Somatic Alterations, Immunotherapy Biomarkers & Associated Treatment Options

KEY  Approved in indication  Approved in other indication  Lack of response

Detected Alteration(s) / Biomarker(s)	Associated FDA-approved therapies	Clinical trial availability (see page 3)	% cfDNA or Amplification
EGFR G719A	 Afatinib  Dacomitinib, Erlotinib, Erlotinib+ramucirumab, Gefitinib, Osimertinib	Yes	4.4%

Variants of Uncertain Clinical Significance  
EGFR N476D (8.1%)  
The functional consequences and/or clinical significance of alterations are unknown. Relevance of therapies targeting these alterations is uncertain.

Additional Biomarkers

Biomarker	Additional Details
MSI-High	NOT DETECTED

Alterations or biomarkers that were "NOT DETECTED" have been excluded from the summary table above.

We evaluated this sample for 74 genes, including the following guideline-recommended genes for NSCLC

EGFR(T790M and others)

ALK

ROS1

BRAF

MET

ERBB2(HER2)

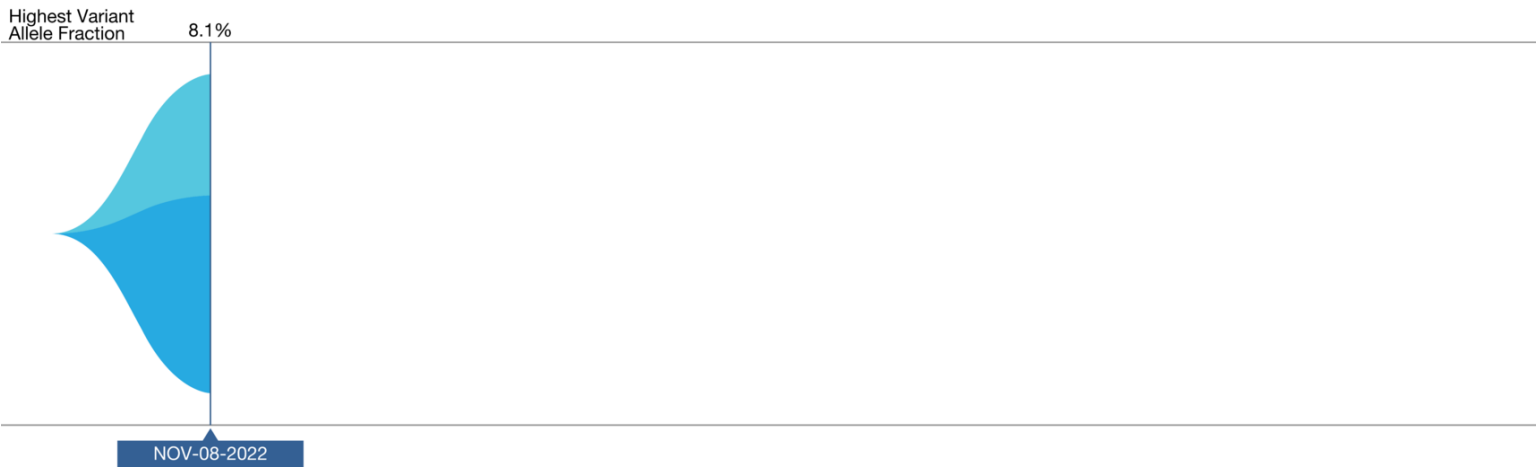
RET

NTRK

KRAS

Guardant360 Tumor Response Map

The Guardant360 Tumor Response Map illustrates the variant allele fraction (% cfDNA) of observed somatic variants at each sample submission. Amplifications are not plotted, and only the first and last five test dates are plotted. Please see the Physician Portal ([portal.guardanthealth.com](https://portal.guardanthealth.com)) for the Tumor Response Map with all test dates.



Detected Alteration(s) / Biomarker(s)	% cfDNA or Amp	
EGFR N476D	8.1%	Variants of Uncertain Clinical Significance §
EGFR G719A	4.4%	

The table above annotates the variant allele fraction (% cfDNA) detected in this sample, listed in descending order.  
§ See definitions section for more detail

Available Clinical Trials (within the same state as the ordering physician)

There may be additional trials not listed here. Visit: [portal.guardanthealth.com](https://portal.guardanthealth.com) or email [clientservices@guardanthealth.com](mailto:clientservices@guardanthealth.com) with A0609834 in the subject line of the email, for additional trials.

Alteration	Trial ID / Contact	Title	Phase	Site(s)
EGFR G719A	NCT02609776 Study Contact,Participate-In-This-Study@its.jnj.com	Study of Amivantamab, a Human Bispecific EGFR and cMet Antibody, in Participants With Advanced Non-Small Cell Lung Cancer	Phase 1	Kaohsiung, Taiwan Taipei City, Taiwan Taipei, Taiwan Taichung, Taiwan (3)
	NCT04077463 Study Contact,Participate-In-This-Study@its.jnj.com,844-434-4210	A Study of Lazertinib as Monotherapy or in Combination With Amivantamab in Participants With Advanced Non-small Cell Lung Cancer	Phase 1	Kaohsiung, Taiwan Taipei City, Taiwan Tainan, Taiwan Taichung, Taiwan
	NCT04721015 ABBVIE CALL CENTER, abbvieclinicaltrials@abbvie.com,844-663-3742	Study of Intravenous (IV) ABBV-637 Alone or in Combination With IV Docetaxel/Osimertinib to Assess Adverse Events and Change in Disease Activity in Adult Participants With Relapsed /Refractory (R/R) Solid Tumors	Phase 1	Kaohsiung, Taiwan Hsinchu City, Taiwan Tainan, Taiwan Taoyuan City, Taiwan
	NCT05099172 Bayer Clinical Trials Contact,clinical-trials-contact@bayer.com,(+)1-888-84 22937	First in Human Study of BAY2927088 in Participants Who Have Advanced Non-small Cell Lung Cancer (NSCLC) With Mutations in the Genes of Epidermal Growth Factor Receptor (EGFR) and/or Human Epidermal Growth Factor Receptor 2 (HER2)	Phase 1	Taipei, Taiwan Taichung, Taiwan

Visit [portal.guardanthealth.com](https://portal.guardanthealth.com) for trials not within the same state as the physician's office

More clinical trial options available at [portal.guardanthealth.com](https://portal.guardanthealth.com)

## Definitions

**Variants of Uncertain Clinical Significance:** The functional consequences and/or clinical significance of alterations are unknown. Relevance of therapies targeting these alterations is uncertain.

## Interpretation

Somatic alterations were detected in the circulating cell-free DNA isolated from this patient's blood specimen. These genomic alterations are cancer-associated somatic variants, some of which have been associated with either increased or reduced clinical response to specific treatments. The percentage of altered cell-free DNA circulating (% cfDNA) in blood is related to the unique tumor biology of each patient. Factors that may affect the % cfDNA of detected somatic alterations include tumor growth, turn over, size, heterogeneity, vascularization, disease progression, and treatment.

Method and Limitations

Guardant360 sequences 74 cancer-associated genes to identify somatic alterations. Cell-free DNA (cfDNA) is extracted from plasma, enriched for targeted regions, and sequenced using the Illumina platform and hg19 as the reference genome. All exons are sequenced in some genes; only clinically significant exons are sequenced in other genes. The types of genomic alterations detected by Guardant360 include single nucleotide variants, gene amplifications, fusions, short insertions/deletions (longest detected, 70 base pairs), and splice site disrupting events (see Table 1). Microsatellite Instability (MSI) is assessed for all cancer types by evaluating somatic changes in the length of repetitive sequences on the Guardant360 panel. A "Not Detected" result in samples where the highest % cfDNA is < 0.2% is an inconclusive result because it does not preclude MSI-High status in tissue. MSI status is currently not reported for earlier panel versions. This version of the Guardant360 test is not validated for the detection of other types of genomic alterations, such as complex rearrangements or gene deletions. Certain sample or variant characteristics, such as low cfDNA concentration, may result in reduced analytic sensitivity. Guardant360 cannot discern the source of circulating cfDNA, and for some variants in the range of ~40 to 60% cfDNA, the test cannot easily distinguish germline variants from somatic alterations. Guardant360 is not validated for the detection of germline or de novo variants that are associated with hereditary cancer risk. Tissue genotyping should be considered when plasma genotyping is negative, if clinically appropriate.

Table 1: Genes on the Guardant360 Panel

Guardant360 reports single nucleotide variants, splice site mutations, and insertion and deletion variants (indels) in all clinically relevant exons in 74 genes and reports other variant types in select genes as indicated below.

AKT1	ALK #	APC	AR †	ARAF	ARID1A	ATM	BRAF †	BRCA1
BRCA2	CCND1 †	CCND2 †	CCNE1 †	CDH1	CDK12	CDK4 †	CDK6 †	CDKN2A
CTNNB1	DDR2	EGFR †	ERBB2 †	ESR1	EZH2	FBXW7	FGFR1 †	FGFR2 # †
FGFR3 #	GATA3	GNA11	GNAQ	GNAS	HNF1A	HRAS	IDH1	IDH2
JAK2	JAK3	KIT †	KRAS †	MAP2K1	MAP2K2	MAPK1	MAPK3	MET †
MLH1	MPL	MTOR	MYC †	NF1	NFE2L2	NOTCH1	NPM1	NRAS
NTRK1 #	NTRK3	PDGFRA †	PIK3CA †	PTEN	PTPN11	RAF1 †	RB1	RET #
RHEB	RHOA	RIT1	ROS1 #	SMAD4	SMO	STK11	TERT ‡	TP53
TSC1	VHL							

‡ Guardant360 reports alterations in the promoter region of this gene.  
# Guardant360 reports fusion events involving this gene.  
† Guardant360 reports amplifications of this gene.

About the Test

The Guardant360 assay was developed and its performance characteristics were determined by Guardant Health, Inc. This test has not been cleared or approved by the U.S. Food and Drug Administration (FDA). The FDA has determined that such clearance or approval is not necessary. This test may be used for clinical purposes and should not be regarded as investigational or for research only. Guardant Health's clinical reference laboratory is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as qualified to perform high complexity clinical laboratory testing. The laboratory report should be interpreted in the context of other clinical information and laboratory, pathology, and imaging studies by a qualified medical professional prior to initiating or changing a patient's treatment plan. The selection of any, all, or none of the drugs associated with potential clinical benefit (or potential lack of clinical benefit) is entirely at the discretion of the treating medical professional. Drug and trial information are based on the diagnosis written on the submitted test request form; this information is not based on any supplemental information provided by the requesting medical professional, including pathology reports or other molecular studies. Some drugs listed in this report may not be approved or cleared by the FDA for the indicated use. Guardant Health makes no endorsement, express or implied, of any product, physician, or procedure contained in this report. This report makes no promises or guarantees that a particular medication will affect (or not affect) the clinical outcome of any patient.

Testing Performed at: Guardant Health

Laboratory Director: Martina Lefterova, MD PhD | CLIA ID: 05D2070300 | CAP #: 8765297 | 505 Penobscot Drive, Redwood City, CA, 94063, USA

### Additional information is available

Any therapeutic annotations are based on publicly available information. This information is described in the "Detailed Therapy Results" and "Relevance of Detected Alterations" sections.

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- Additional clinical trials
- Detailed Therapy Results
- Relevance of Detected Alterations
- References

If you would like to receive this additional information with every Guardant360 report, please call client services at [855.698.8887](tel:855.698.8887) to opt-in.