康誠生技
Genconn Biotech

GUARDANT

Guardant

基因檢測服務報告

檢測項目：	**Guardant360 液態活體癌症基因檢測**
醫師姓名：	江起陸
受檢者姓名：	羅以珊
送檢編號：	A1232241
檢測次數：	第二次

提醒

基因數據乃屬個人隱私，切勿輕易向任何個人、團體或非您的授權者透漏本報告內容。若您有任何疑慮，歡迎來電洽詢，我們很樂意為您提供更詳細的諮詢服務。若因郵遞錯誤收此檔，請予銷毀，多謝合作。

康誠生技股份有限公司 客戶服務中心

諮詢時間｜週一～週五 9:00～17:00 （國定假日除外）
諮詢專線｜02-55696099
客服信箱｜service.gb@healthconn.com

REPORTING

Original Reported Date:	DEC-11-2024
Amended Date:	DEC-16-2024
Receipt Date:	DEC-06-2024
Collection Date:	DEC-04-2024
Specimen:	Blood
Status:	AMENDED

PHYSICIAN

Chi-Lu Chiang
Account: Welgene Biotech Co., Ltd.
Address: 12F No.3 Park St., Nangang Dist., Taipei City, 11503, Taiwan
Ph: N/A | Fax: N/A
Additional Recipient: N/A

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

Detected Alteration(s) / Biomarker(s)	Associated FDA-approved therapies	Clinical trial availability	% cfDNA or Amplification
No tumor-related somatic alterations were detected in this patient's sample. This may be due to either absence of detectable mutations in the tumor itself or, more commonly, low levels of circulating tumor-derived cell-free DNA (ctDNA). Low ctDNA levels are most often encountered in patients with early stage or low volume disease, patients responding to therapy, and/or patients with stable disease. Clinical correlation is recommended with consideration for repeat Guardant360 testing of a new plasma or tissue sample when appropriate.			

Comments

Amended Report: On the report released on DEC-11-2024, the report was listed as Test Number 1 and the Tumor Response Map (TRM) and alteration trend lines did not show the results for the current draw on DEC-04-2024. In this amended report, the report Test Number has been updated to 2 and the results for the current draw are now included on the TRM and alteration trend lines. There are no other changes to this report.

Reported by: JP1,AA23

Additional Biomarkers

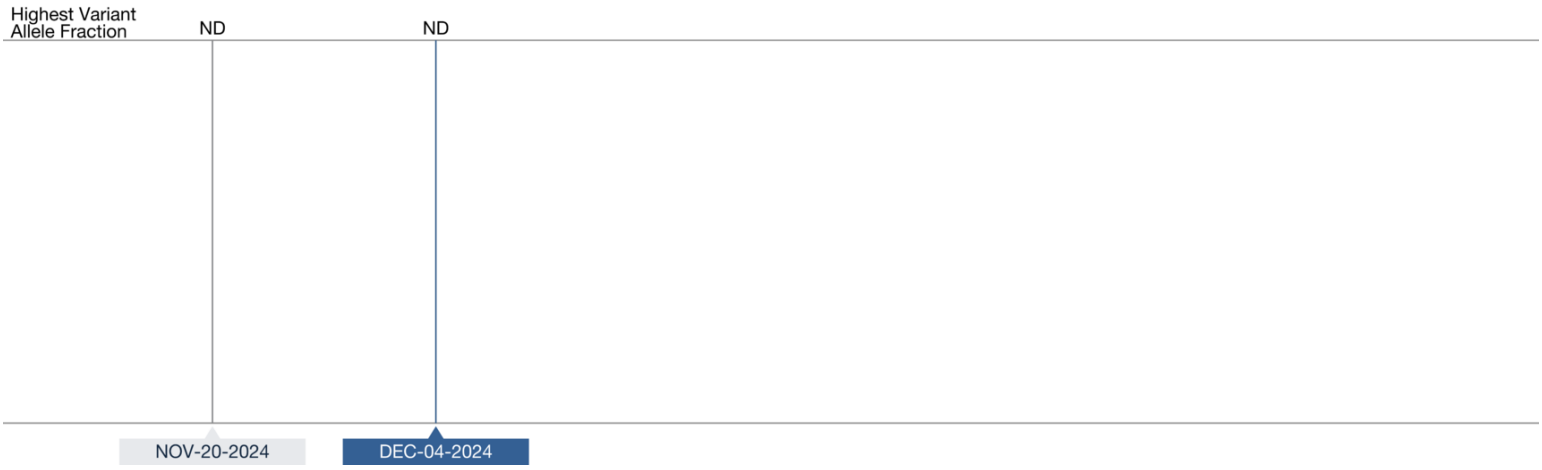
Biomarker	Additional Details
MSI-High	NOT DETECTED

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**) for the Tumor Response Map with all test dates.



Definitions

Somatic Alterations Not Detected (ND): Somatic alterations may be present that are below the limit of detection of this test. Certain sample or variant characteristics may result in reduced analytic sensitivity. The absence of detectable somatic alterations in circulating cell-free DNA does not preclude the presence of somatic alterations in the tumor.

Interpretation

Somatic alterations were NOT detected in the circulating cell-free DNA isolated from this patient's blood specimen. Table 1 describes the types of genomic alterations detected by Guardant360. 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.

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

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