natera™ | Signatera™
Residual disease test (MRD)

ABOUT THIS TEST:

Signatera™ is a bespoke mPCR-NGS assay for detection of circulating tumor DNA (ctDNA) in the plasma of patients previously diagnosed with cancer. Individual-specific mutation signatures are identified by up front tissue and matched normal whole exome sequencing.

Designed on Exome

Patient & Sample Information

Patient Name:
Date of Birth:
Medical Record #:
Case File ID:
Cancer Type:
Tissue Collected:
Tissue Received:
Plasma Collected:
Plasma Received:
Block ID:
Block Type:

Ordering Physician

Name:	N/A
Clinic:	Genomed Company
NPI:	N/A
Address:	Leninskaya Sloboda St., Build 26, Office 318, Moscow 115280, RU
Pathology Lab Name:	Genomed Company - Oncology, LCC, Russia
Additional Reports:	N/A
Report Date:	

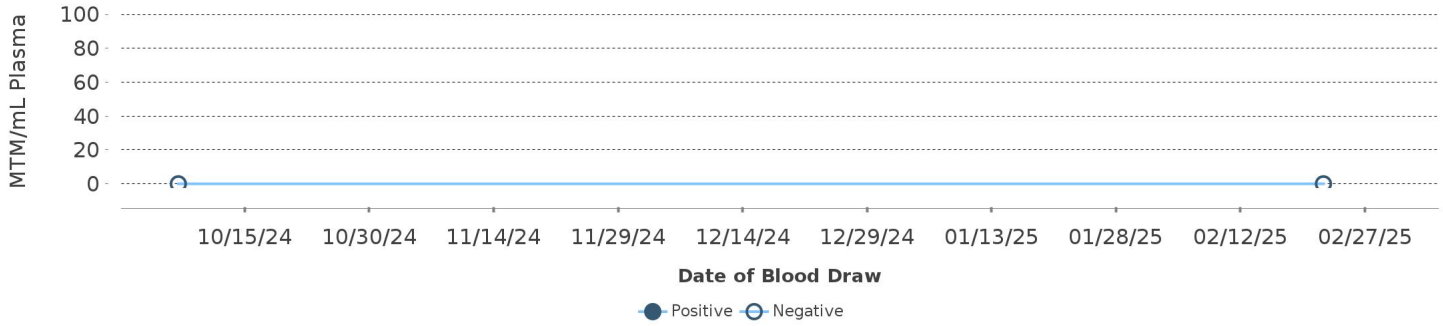
FINAL RESULTS SUMMARY

Signatera Negative

MTM/mL: Not Detected

Mean tumor molecules per mL is calculated based on the mean of ctDNA molecules detected per mL of the patient's plasma. ***See Limitations section below.***

Historical Results



Date	Reported MTM/mL
	0.00
	0.00

Interpretation and Limitations

Signatera is a personalized, tumor-informed test for the longitudinal detection of circulating tumor DNA (ctDNA). Interval testing is recommended for all patients. Studies have demonstrated that when ctDNA is detected (Signatera Positive) following surgery or definitive treatment, the risk for disease relapse is high without further treatment. Conversely, when ctDNA is not detected, the patient may be considered at lower risk for relapse. For those with multiple timepoints, upward trending ctDNA levels are suggestive of increasing tumor burden (1,2). For a single time point in isolation, the absolute MTM/mL value has no known clinical significance and should not be compared across patients. Test results should be interpreted in context of other clinicopathological features. ctDNA detection sensitivity may be limited due to blood collection within two weeks of surgery and while the patient is on therapy. Signatera is a quantitative test and reports in units of mean tumor molecules per ml (MTM/mL), which is comprised of three measured components (plasma volume, cell free DNA (cfDNA) concentration, and Variant Allele Frequency (VAF)). The MTM/mL number will be qualified if any measured component falls outside the analytical measurement range for that component. The analytical sensitivity is 95% at the limit of detection (0.3 MTM/mL). Results obtained are specific to the assessed time point. A negative test result does not definitively indicate the absence of cancer. This test is not designed to detect or report germline variation, nor does it infer hereditary cancer risk for the patient. Each Signatera assay is designed to a single tumor for a given patient. At this time, multiple personalized Signatera assays cannot be developed for the same patient. This test is designed to detect ctDNA from the assayed tumor only; new primary tumors will not be detected. There is a low risk that a new primary may share a variant that could interfere with the Signatera test. Testing cannot be performed in patients who are pregnant, have a history of bone marrow transplant, or history of blood transfusion within three months. This test is expected to have limited sensitivity in cancer types such as GIST, renal cell carcinomas, primary brain tumors, and lymphoma due to limited ctDNA shed.

[1] Bratman SV, Yang SYC, Iafolla MAJ, et al. Personalized circulating tumor DNA analysis as a predictive biomarker in solid tumor patients treated with pembrolizumab. Nature Cancer. 2020;1(9):873-881

[2] Henriksen TV, Tarazona N, et al., Circulating Tumor DNA in Stage III Colorectal Cancer, beyond Minimal Residual Disease Detection, toward Assessment of Adjuvant Therapy Efficacy and Clinical Behavior of Recurrences. Clin Cancer Res. 2021; 28(3):507-517

Methodology

FFPE samples are reviewed by a pathologist to assess tumor content and percent tumor nuclei. Tumor DNA is extracted using Omega Bio-tek Mag-Bind® FFPE DNA/RNA kit. Whole genomic DNA is isolated from peripheral blood using QIAamp DNA Blood MiniKit to provide DNA for germline sequencing. Circulating tumor DNA (ctDNA) is extracted from plasma derived from whole blood samples collected in cell-free DNA blood tubes (Streck) using the QIAsymphony automated or manual extraction method (Qiagen). Whole-exome sequencing is performed on tumor and peripheral blood DNA using the Natera whole-exome sequencing assay. Using a proprietary algorithm, putative, clonal variants present in the tumor but absent in the germline DNA are identified to design the customized multiplex PCR assay. The customized PCR assays are run to detect presence or absence of these variants within circulating plasma. A patient's plasma sample is considered ctDNA positive when at least two individual-specific tumor variants are detected. When fewer than two individual-specific tumor variants are observed, a negative result is issued. Pathology services and whole exome sequencing is performed at Natera Inc.(CLIA ID# 05D1082992), 201 Industrial Rd. Suite 410, San Carlos, CA 94070, USA.

Disclaimer

The extraction, library preparation, and sequencing for this test were performed by Natera Inc., 201 Industrial Rd. Suite 410, San Carlos, CA 94070 (CLIA ID 05D1082992). The data analysis and reporting for this test were performed by Natera Inc., 201 Industrial Rd. Suite 410, San Carlos, CA 94070 (CLIA ID 05D1082992). This test was developed and its performance characteristics determined by Natera Inc. The test has not been cleared or approved by the U.S. Food and Drug Administration (FDA). CAP accredited, ISO 13485 certified, and CLIA certified. Pathology services and whole exome sequencing for this test were performed by Natera Inc., 201 Industrial Rd. Suite 410, San Carlos, CA 94070 (CLIA ID 05D1082992).

This report was released under the autoverified process under the supervision of Tanner Hagelstrom, Ph.D. MBA, FACMG
CLIA Laboratory Director: J. Dianne Keen-Kim, Ph.D., FACMG, HCLD(ABB)