Patient & Sample Information

Subject Name:	Doe Jane
Date of Birth:	02/01/1980
Medical Record #:	Medical Record #
Case File ID:	101
Cancer Type:	TNBC
Tissue Collected:	01/29/2016
Tissue Received:	01/31/2016
Plasma Collected:	09/17/2017
Plasma Received:	09/19/2017

Ordering Physician

Name:	Dr. Matthew Goodbirth, M.D. (G123456)
Clinic:	Natera, Inc.
NPI:	123456789
Address:	201 Industrial Road, Suite 410, San Carlos, CA 94070
Additional Reports:	Some Delivery Instructions
Report Date:	02/04/2019

signatera
PERSONALIZED LIQUID BIOPSY
POWERED BY NATERA®

ABOUT THIS TEST:

Signatera™ is an individual-specific 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 upfront tissue and matched-normal whole exome sequencing.

FINAL RESULTS SUMMARY

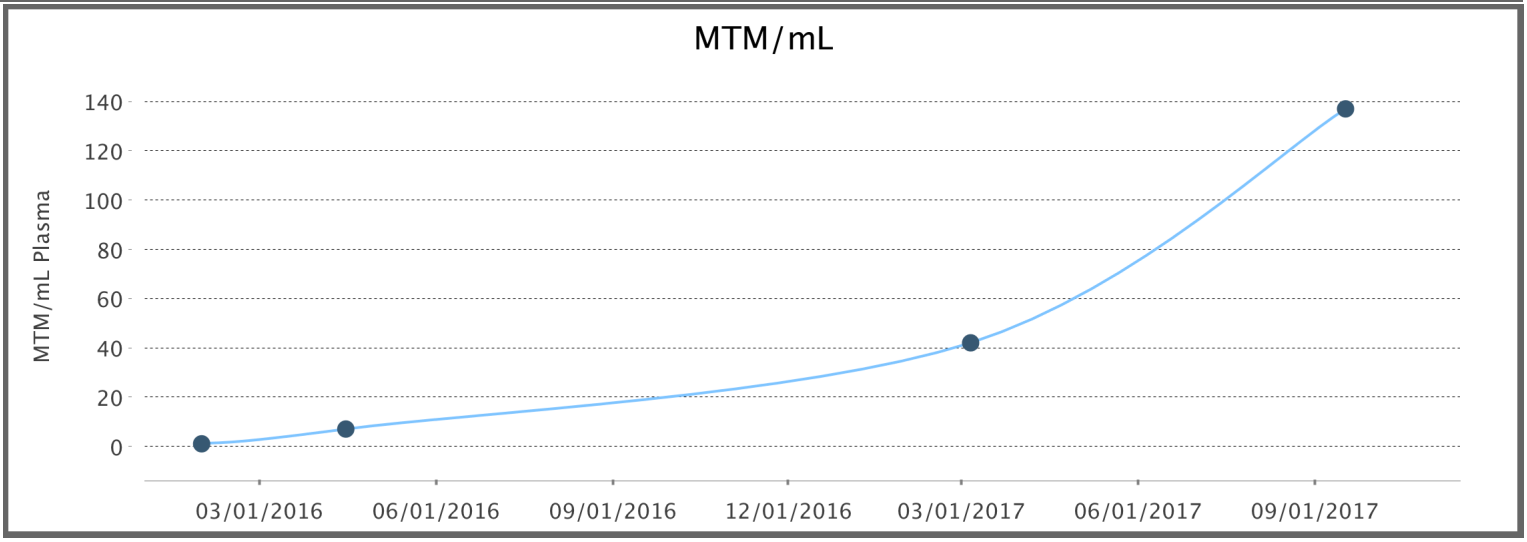
Signatera Positive

Date: 09/17/2017
MTM/mL: 137

Mean tumor molecules per mL is calculated based on the mean of ctDNA molecules detected per mL of the patient's plasma.

Test Clinical Notes

Historical Results



Date	01/31/2016	04/15/2016	03/06/2017	09/17/2017
MTM/mL	1	7	42	137

Interpretation and Limitation

This test has been validated for use in patients with colorectal, bladder, lung and breast cancer. The test cannot be run on patients with concurrent malignancies, who are pregnant, who have a history of bone marrow transplant, history of blood transfusion within three months. Signatera is a screening test, is not diagnostic, and does not infer therapeutic choice. All results should be interpreted by a clinician.

Methodology

FFPE samples are assessed by a pathologist to identify tumor margins and percent tumor content. DNA is extracted using Qiagen AllPrep. Whole genomic DNA is isolated from peripheral blood using QIAamp DNA Blood Mini Kit to provide a baseline DNA sequence. Circulating tumor DNA is extracted from plasma collected in Streck tubes using Natera's proprietary methods. Whole-exome sequencing using KAPA HyperPrep library kit (Roche) with a custom xGen exome capture (IDT) is performed to identify tumor DNA sequence using a proprietary algorithm. Sixteen putative clonal variants present in the tumor but absent in the baseline DNA form the basis for individual-specific PCR-based assays. Individual-specific PCR assays are run to detect presence or absence of circulating tumor DNA (ctDNA). 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. Results obtained are specific to the assessed time point. A positive test result does not indicate a clinical diagnosis of cancer. A negative test result does not indicate remission. This test is not designed to detect or report germline variation, nor infer hereditary cancer risk for the patient. Tumor variation outside of the sixteen individual-specific tumor variants are not assessed. Pathology services and whole exome sequencing were performed at Ashion Analytics, Phoenix, AZ and reported on 04/01/2017

Disclaimer

This test was developed and its performance characteristics determined by Natera, Inc. (CLIA ID #05D1082992) as required by the CLIA '88 regulations. It has not been cleared or approved by the U.S. Food and Drug Administration (FDA), but due to enforcement discretion by the FDA, FDA clearance or approval is not necessary at this time.

Approved by: J. Dianne Keen-Kim, Ph.D., FACMGG, Senior Laboratory Director