MRDVision

John Smith
Patient ID: H23/028662

Patient

Name: John Smith
Patient ID: H23/028662
Sex at birth: Male
Date of birth:

Physician

Name: John Doe
Institution:

Contact: +82-10-0000-0000
Address:
1600 Amphitheatre Parkway, Mountain View, CA 94043

MRD Specimen

Specimen ID:
Specimen type: Blood(plasma)
Collected:
Received:

Reference Sample

Accession ID:

Diagnosis:
Pancreatic neuroendocrine tumor, nonfunctioning
Reference (tumor) obtained:
Jan 20, 2017
Number of somatic variants of cancer used: 113K

Test Information

Test methodology:
Tumor genome-informed genome MRD test
Estimated Limit of Detection (LoD): 1 ppm
Adequacy (cfDNA):
Satisfactory
Sequencing mean depth:
101.3x

CURRENT TEST RESULT

• DETECTED **Circulating tumor DNA(ctDNA) is detected.**

Collected Date: Feb 07 2024
Estimated tumor fraction: 420 ppm

TIMELINE

Collected Date	ctDNA	Estimated tumor fraction
Feb 07 2016	NOT DETECTED	-
Feb 07 2017	NOT DETECTED	-
Feb 07 2018	NOT DETECTED	-
Feb 07 2019	DETECTED	3.2 ppm
Feb 07 2020	DETECTED	410 ppm
Feb 07 2021	NOT DETECTED	-
Feb 07 2022	NOT DETECTED	-
Feb 07 2023	DETECTED	3.3 ppm
Feb 07 2024	DETECTED	420 ppm

'Detected' indicates that a significant presence of circulating tumor DNA has been observed above the established limit of blank (LOB). The LOB refers to the concentration of ctDNA that can be reliably distinguished from background noise.

TEST DESCRIPTION

MRDVision is a whole genome sequencing (WGS) personalized, tumor-informed test designed for the longitudinal detection of circulating tumor DNA (ctDNA) in the plasma of patients previously diagnosed with cancer. Individual-specific mutation profiles are identified through CancerVision test, allowing for precise monitoring of ctDNA over time.

Methodology: Cell-free DNA (cfDNA) is extracted from peripheral blood collected in Streck tubes using the KingFisher Apex and prepared using the Twist cfDNA library prep kit. The libraries are sequenced using the UG100 platform to detect the presence or absence of variants identified through previous CancerVision testing within a patient's circulating plasma. The mean genome-wide sequencing read-depth is 90x (at least 80x). This test assesses the presence of tumor DNA by counting tumor-supporting reads among background (non-tumor) reads. A positive or negative result is determined by evaluating the likelihood of the observed data under the null hypothesis (no tumor DNA in the plasma) using the error rate and number of total reads, collectively referred to as the limit of blank (LOB).

Tumor fraction is the estimated fraction of ctDNA among total cfDNA in plasma.

Limit of Detection (LOD95) is defined as the lowest tumor fraction at which 95% of true positive samples are expected to be detected as positive. In other words, if a sample contains tumor DNA at the LOD95 level, this test will call it positive in 95% of cases. It should be noted that, under the LOD95 definition, tumor fractions below the LOD95 may still yield a positive result, though with lower probability.

Test results should be interpreted within a clinical context. ctDNA detection sensitivity may be limited due to blood collection within two weeks of surgery and while the patient is on therapy. The sensitivity of this test is influenced by the number of markers derived from somatic variations identified through CancerVision.

Testing cannot be performed in patients who are pregnant, have a history of bone marrow transplant, or have had a blood transfusion within three months. This test is expected to have limited sensitivity in cancer types such as GIST, renal cell carcinoma, brain tumors, and lymphoma due to limited ctDNA shed.

DISCLAIMER

This test was developed and its performance characteristics were determined by Inocras. It has not been cleared or approved by the US Food and Drug Administration.

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TRACKING INFORMATION

Accession ID:
Analysis ID:
Pipeline version: MRD 1.0.0
PRT.013 Rev1.0