NeXT Personal® Dx

Patient: John Doe
Report Released: 01/04/23
Accession Number : MAK5573
DOB: 01/01/01 **MRN:** 123456789

ctDNA assay for Molecular Residual Disease (MRD) detection

NeXT Personal Dx Report

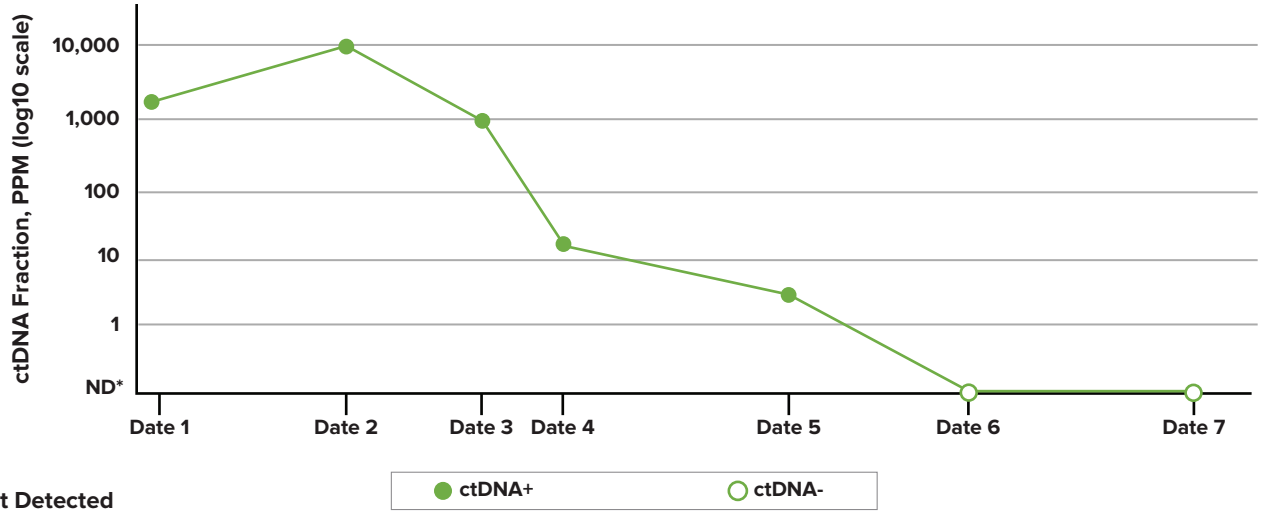
Ordering Clinician	Specimen	Patient
Referring Physician: Richard Miles **Clinic/Institution:** Affiliated Clinical Laboratory **Address:**	**Tissue Collection:** 10/03/22 **Tissue Received:** 10/10/22 **Plasma Collected:** 12/04/22 **Plasma Received:** 12/06/22 **Accession #:** MAK5573 **Tissue ID #:**	**Name:** John Doe **DOB:** 01/01/01 **Birth Sex:** M **MRN:** 12345678 **Diagnosis:** Colon Adenocarcinoma **Primary Tumor Site:** Colon

I. ctDNA RESULTS SUMMARY

ctDNA Status	ctDNA Fraction, PPM	
12/04/2023 **Not Detected**	**Not Applicable**	**Parts Per Million (PPM):** The number of tumor molecules observed per one million total molecules sequenced.

II. ctDNA HISTORICAL RESULTS

Longitudinal Results



* Not Detected

Result History

Date 7	**Not Detected**
Date 6	**Not Detected**
Date 5	**4 PPM**
Date 4	**22 PPM**
Date 3	**910 PPM**
Date 2	**9,499 PPM**
Date 1	**1,845 PPM**

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III. ABOUT THE PERSONALIS NEXT PERSONAL DX TEST

Interpretation: The presence of ctDNA after treatment has been associated with a higher risk of cancer recurrence in the absence of additional therapy. However, a “Not Detected” test result may not indicate the absence of cancer. Retesting at regular intervals is recommended.

Test Details: The NeXT Personal Dx Test is a personalized tumor-informed liquid biopsy assay designed to detect molecular residual disease (MRD) using circulating tumor DNA (ctDNA) from patients previously diagnosed with a solid tumor cancer. Individualized molecular profiles are established by upfront tissue and matched normal whole genome sequencing (WGS). The assay delivers high ctDNA sensitivity down to the 1-3 parts per million (PPM) range by tracking up to 1800 somatic variants in a personalized patient panel. However, the ability to detect ctDNA may be affected by the quality and quantity of tumor DNA obtained from formalin-fixed paraffin-embedded (FFPE) samples and cell-free DNA (cfDNA) obtained from blood samples. Therefore, each time point typically has minor variations for the detection threshold. Status calls are determined by a p-value threshold established during assay analytical validation: ctDNA detected, $p \leq 0.001$ and ctDNA not detected, $p > 0.001$. Thus, the assay operates at high specificity, 99.9%, with a false positive rate of less than 0.001 per run (data on file with Personalis. Please visit www.personalis.com/for-providers/next-personal-dx/ for clinical performance data).

The NeXT Personal Dx test is a laboratory developed test (LDT) and is performed in a CLIA/CAP accredited laboratory. The test was developed and its performance characteristics determined by the Personalis Clinical Laboratory. It has not been cleared or approved by the United States Food and Drug Administration (FDA). The Personalis Clinical Laboratory is regulated under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as qualified to perform high-complexity clinical testing. This test is used for clinical purposes and results in this test report are subject to the terms of the Patient Consent Document given to the patient by the physician. Results should not be regarded as investigational or for research. Pursuant to CLIA requirements, this laboratory has verified its accuracy and precision. Genetic testing using the Methods applied by the Personalis Clinical Laboratory is in accordance with applicable regulatory requirements, test accuracy and methodology performance specifications (see Test Performance Specifications Section, visit www.personalis.com or contact us for further information regarding the Methodology and Limitations of this test).

Treatment Decisions are Responsibility of Physician: The testing services provided by Personalis and the results of those services presented in this report are intended for use solely as tools to assist a qualified healthcare professional. Results should not be used to replace or overrule a qualified, licensed health care provider's judgment, clinical diagnosis, or monitoring of cases. Any diagnosis or treatment decisions made as a result of data presented in this report should be made in combination with other patient health information and regulatory guidance. Information contained within this report is current as of the date of the report.

Limitations: The performance has been established in accordance with CLIA, however the accuracy of individual results cannot be guaranteed. The NeXT Personal Dx Test is intended to be used to detect ctDNA, but its results are not diagnostic. A “ctDNA Detected” result is not a definitive diagnosis of disease recurrence and should be interpreted in the context of the available clinical information by the treating clinician. A “ctDNA Not Detected” result does not rule out the presence of ctDNA, and individuals who receive this result should be continue following all treatment recommendations from their qualified health care providers. The use of the NeXT Personal Dx Test should not replace, supersede, or otherwise alter the use or frequency of medically established cancer detection modalities. The chance of a false positive or false negative result, due to laboratory errors incurred during any phase of the testing (pre-analytical, analytical, or post-analytical), cannot be excluded. The manner in which the services generate results, reports, and other information is complex, dependent upon operator accuracy, pre- and post-analytical factors, and the possibility of software or other error cannot be completely eliminated. Personalis does not provide any express or implied warranty as to the accuracy of results provided, or the outcomes from their use.

Disclaimers: Associated Pathology Medical Group Inc. (APMG), located at 105A Cooper Court, Los Gatos, CA 9503; Phone: 408-399-5050, has provided Personalis with a histopathology analysis on this specimen for the purpose of assessing tumor content. The final report from APMG is on file with Personalis and is available upon request.

Electronically signed by:

Date: MM/DD/YY

Juan-Sebastian Saldivar, MD, FACMG
Laboratory Medical Director

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