TrueMRD™ Monitoring Test for MIBC

Patient Report

PATIENT

Name: **Sample Patient Name**
Date of Birth: **01/01/1955**
Medical Record #: **123456789**
Cancer Type: **Muscle-invasive Bladder Cancer**

SPECIMEN INFORMATION

Order Date: **05/05/2026**
Specimen Type: **Whole Blood**
Specimen Collection Date: **05/04/2026**
Specimen Received Date: **05/05/2026**
Order Number: **00000001**

ORDERING CLINICIAN

Name: **Sample Clinician, MD**
Practice: **Sample Practice**
Address: **123 Birch Avenue, Suite A, Anytown, CA 54321**

TrueMRD TEST RESULT

MRD NEGATIVE (-)

Specimen Type	Collection Date	MRD Status
Whole Blood	05/04/2026	Not Detected

Interpretation: Minimal residual disease was not detected.

PATIENT HISTORICAL RESULTS

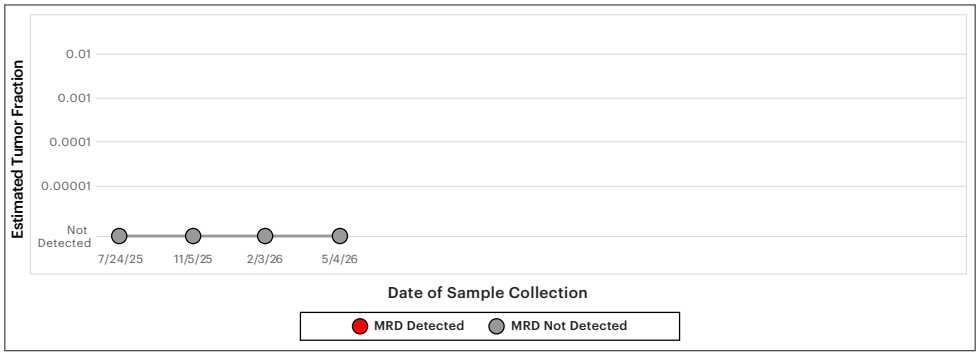
Tissue Specimen Summary	
Collection Date: 01/09/2025	**PSTS* Generation Date:** 07/27/2025

Blood Specimen Summary	
Collection Date	**MRD Status**
05/04/2026	**Not Detected**
02/03/2026	Not Detected
11/5/2025	Not Detected
07/24/2025	Not Detected

*PSTS=Patient Specific Tumor Signature

ADDITIONAL INFORMATION

Disclaimer: The TrueMRD Test is analytically validated as a qualitative assay to detect the presence or absence of minimal residual disease (MRD). When MRD is detected, an Estimated Tumor Fraction (eTF) is reported to provide additional context. The eTF has not been clinically validated for predicting treatment response or patient outcomes and should not be used for clinical decision-making. Analytical sensitivity studies demonstrate detection of tumor-derived ctDNA at or above the LOD for Tumor Fraction (TF) of 0.0001, with ≥95% sensitivity. In some cases, a positive MRD Detection call may be associated with an eTF below the analytical LoD of 0.0001, as the MRD Detection algorithm generates a detection score based on features integrated across whole genome sequencing data.



Approved By:
E-SIGNED BY NAME, CREDENTIAL ON DATE AT TIME

CLIA ID Veracyte Labs SSF# 05D2014120
CLIA ID Veracyte Labs SD# 05D2055897
Lab Director: [Lab Director Name, MD]

A copy of this form shall be as valid as the original. This test was developed and its performance characteristics determined by Veracyte Labs SSF. The laboratory is regulated under CLIA '88 as qualified to perform high complexity clinical testing. This test has not been cleared or approved by the FDA. This test is used for clinical purposes and clinical correlation of its results are recommended. It should not be regarded as investigational or for research.

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TEST DESCRIPTION

The TrueMRD Monitoring Test for MIBC is a tumor-informed whole-genome sequencing-based assay designed to detect minimal residual disease (MRD) in patients diagnosed with muscle-invasive bladder cancer (MIBC).

Specimen Requirements:

- Tumor Tissue: Formalin-Fixed Paraffin-Embedded (FFPE).
- Whole Blood:
  - Buffy Coat for isolation of matched germline (normal) DNA.
  - Plasma for isolation of circulating cell-free DNA (cfDNA).

The Test Provides Results in a Binary Format:

- MRD Positive: Indicates that minimal residual disease was detected.
- MRD Negative: Indicates that minimal residual disease was not detected.

Results should be interpreted by a qualified healthcare professional in the context of the patient's clinical and pathological history. Test results are intended to aid in clinical decision-making in alignment with professional guidelines and alongside other clinicopathological factors.

TEST METHODOLOGY

The TrueMRD Test utilizes whole genome sequencing on three sample types from a single patient:

- Genomic DNA extracted from FFPE tumor tissue
- Genomic DNA extracted from the buffy coat (matched normal), isolated from whole blood
- Cell-free DNA extracted from plasma

During the initial baseline test, a patient-specific tumor signature (PSTS) is established by identifying tumor-specific variants, mutations present in the tumor tissue but absent in the matched normal sample. This signature is derived from comparative WGS analysis of the FFPE tumor and buffy coat samples.

Subsequently, the PSTS is used to interrogate ctDNA within the cfDNA sample from plasma. A proprietary algorithm generates a detection score, which is compared against a predefined threshold to determine MRD status. Results are reported in a binary format: MRD positive and MRD negative as defined above.

When MRD is detected, an estimated tumor fraction (eTF) is reported to provide additional context. The TrueMRD Monitoring Test has an analytical sensitivity of ≥95% at the lower limit of detection (LOD) of 0.0001 TF.* Because the proprietary MRD Detection algorithm generates a detection score based on integrated features across whole genome sequencing data, a positive MRD Detection call may be associated with an eTF below 0.0001.

*This means that if DNA from the original tumor is present in the blood at a ratio of 1 tumor DNA fragment to 20,000 total DNA fragments (representing a TF of 0.01%), the test will detect it and report "MRD Detected" in at least 19 out of 20 cases. Analytical validation data are available upon request.

CONTRAINDICATIONS / LIMITATIONS

- Results reflect the assessed time point only.
- A negative result does not definitively indicate the absence of cancer.
- The test is designed to detect circulating tumor DNA (ctDNA) specific to a single known tumor per patient.
- Testing cannot be performed on patients who have concurrent malignancies, are pregnant, have a history of bone marrow transplant, or have received a blood transfusion within three months prior to blood collection.
- Test results should be interpreted within the clinical context by a licensed healthcare provider directly involved in the patient's care.
- Blood collection within two weeks of surgery or while the patient is being treated may reduce ctDNA detection sensitivity.

REFERENCES

1. Nordentoft, I. et al. Eur Urol 86, 301-311, (2024). 10.1016/j.eururo.2024.05.014
2. Zviran, A. et al. Nat Med 26, 1114-1124, (2020). 10.1038/s41591-020-0915-3.