

Patient: Holmes, Timothy

ODDx Accession #: OD2101001

Date of Birth: 12/17/1972 Gender: M

Specimen: Whole Blood

Referring Physician: Dr. Leroy Vaden

Draw Date, Time: 11/20/2020, 3:45:00 PM

Referring Institution: Willowdale Hospital, Yorktown, TX

Received Date: 11/21/2020

Circulating Tumor Cells (CTC's) by Menarini's CELLSEARCH[®] System for: Prostate Cancer

Number of CTC's: 0 per 7.5 mL of Blood

Interpretation: The results of this test are **Favorable** (≥ 5 CTC's/7.5 mL of blood). A result of 5 or more per 7.5 mL of blood at any time during the course of this disease is associated with a poor prognosis and is predictive of shorter progression free survival and overall survival.

Reportable Range: 0-1238 CTC's

Reference Range: 0-1 (determined with cancer-free healthy volunteers)

Test Method, Specification and Limitations:

- Cancer metastasis occurs when cancer cells shed. The CELLSEARCH[®] CTC Test is the first and only clinically validated, FDA-cleared blood test for enumerating circulating tumor cells (CTC's) using the CELLTRACKS ANALYZER II[®], a semi-automated fluorescence microscope. The assay enumerates only those cells that express the Epithelial Cell Adhesion Molecule (EpCAM) and cytokeratins (CK) 8, 18, and/or 19.

Conditions of Specimen that Limit Adequacy of Testing:

- The results of a CELLSEARCH[®] test should be interpreted with caution if specimens are drawn within 7 days of administration of doxorubicin therapy. CTC's that do not express EpCAM will not be detected by the CELLSEARCH[®] test. CTC's that express EpCAM but not cytokeratins 8, 18, and 19 will not be detected by the CELLSEARCH[®] test.

CTC's are a strong, independent predictor of overall and progression-free survival in metastatic breast, prostate and colorectal cancer. Throughout therapy at any given time, CELLSEARCH[®] CTC testing can be used to monitor a patient's status by showing the patient's prognosis on a particular therapy as being favorable or unfavorable.

Serial testing for CTC's should be used in conjunction with all clinical methods for monitoring, such as imaging, lab tests, physical examination, and complete medical history in accordance with appropriate patient management procedures to assess patient prognosis throughout the course of disease.

CELLSEARCH[®] is manufactured by Menarini Silicon Biosystems, Inc.

For more information: www.OncoDecision.com or www.cellsearchctc.com.

Lab Test performed by:

Onco-Decision Diagnostics, LLC

11142 Hopes Creek Rd., College Station, TX 77845

Lab Director: Wenli Zhou, PhD, HCLD

CLIA: 45D2192361