Nordic Laboratories

PATIENT: XXXXXXXXXXXXXX			TEST REF: GNL-NL-XXXXX
TEST NUMBER: G-NL-XXXXX	COLLECTED: 00-XXX-2024		PRACTITIONER: XXXXXXXXXXXXX
GENDER: XXXXXX	RECEIVED: 00-XXX-2024		
AGE: XX	TESTED: 00-XXX-2024		XXXXXXXXXXXXXXXXXXXXX

TEST NAME: trublood® - Prostate

Summary and Interpretation

Test result for Circulating Tumor Cells (CTCs)

☐ Negative ☑ Positive

Type of Tumor

☑ Probability of carcinoma (Adenocarcinoma) ☐ Indeterminate ☐ Not Applicable

Summary of Immunocytochemistry Analysis

EpCAM [+] PanCK [+] PSMA [+] CD45 [-] AMACR [-]

P63 [-]

[+] Positive, [-] Negative

Test Interpretation and Advice

Please note that the results of this test are not to be used as the sole means of diagnosis. This should be used as a triaging tool and is not intended to substitute standard of care procedures. Please also be mindful of the limitations of the test which include the possibilities of 'false positives' and 'false negatives' due to biological variations beyond the performance spectrum of the test.

Circulating Tumor Cells (CTCs) indicative of Trublood positivity were detected in the submitted sample. This is suggestive of higher risk of detection of adenocarcinoma of prostate. Individual is advised to consult a physician for further guidance to undertake follow-up investigations.

Guide to Interpretation of Test Results

Trublood prostate test analyzes Circulating Tumor Cells (CTCs) in peripheral blood and is intended to aid in the diagnosis of Adenocarcinoma of prostate.

- "Negative"
  CTCs indicative of trublood prostate positivity, were not detected in the submitted sample. Please be mindful that a negative Trublood prostate report does not completely rule out the possibility of prostate cancer as some tumors may not shed a sufficient number of detectable cells in the blood.
- "Positive"
  CTCs indicative of trublood prostate positivity were detected in the submitted sample. Individuals with positive test result are advised to consult their physician / clinician for appropriate guidance / diagnostic workup as per Standard of Care.

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- "Indeterminate"
  Type of tumor could not be determined.

Methods

Peripheral Blood Mononuclear Cells (PBMCs) are isolated from the blood sample and are treated with a proprietary CTC enrichment medium (CEM), which is selectively toxic towards nonmalignant (epithelial, endothelial and hematolymphoid) cells and permits malignant cells (CTCs) to survive. Surviving apoptosis reluctant cells and clusters are characterized by fluorescent immunocytochemistry (fICC) profiling to determine the status of various markers (see following sections). These markers help identify CTCs as well as determine the type of tumor and the likely organ of origin. Quantitative fluorescence imaging is performed on Cell Insight CX7 High-Content Screening Platform (ThermoFisher Scientific).

Immunocytochemistry Markers (Internally Validated)

Marker (Clone)	Marker (Clone)	Marker (Clone)	Marker (Clone)
EpCAM (REA764)	PanCK (REA831)	PSMA (3149R)	CD45 (REA747)
AMACR (13H4)	P63 (DAK-p63)		

Clinical Performance

The non-invasive Trublood Prostate test for Prostate Cancer is a 'Single Laboratory Developed Test' for diagnosis and management of Prostate Cancer. The test has been validated by Datar Cancer Genetics through the 'RESOLUTE' and 'TRUEBLOOD' clinical trials (Registration No. CTRI/2019/01/017219 and CTRI/2019/03/017918 respectively).

The test has a detection rate (Sensitivity) of > 99% as evaluated on samples from 90 Prostate cancer patients. The test has a specificity of 99.3% and > 99% as determined by evaluation of 289 cases diagnosed with benign prostate conditions and 3898 asymptomatic individuals, respectively.

Circulating Tumor Cells (CTCs) which are defined as cells in the peripheral blood that are EpCAM and PanCK positive and CD45 negative are harvested using a proprietary medium and are characterized using panel of antibodies (please see table). For our publications pertaining to Trublood Prostate, please visit https://trublood360.com/publications/.

Trublood Prostate test has been validated for evaluation of risk of detection for Adenocarcinoma of Prostate. Few rare histopathological subtypes cannot be determined due to lack of antibody specificity.

Information to Patients

The Trublood prostate test is a Laboratory Developed Test, and its performance characteristics are determined by Datar Cancer Genetics UK Private Limited, United Kingdom. It has not been cleared or approved by the U.S. Food and Drug Administration.
The processing of samples is carried out in Datar Cancer Genetics UK Private Limited, United Kingdom. This laboratory is registered under the Clinical Laboratory Improvement Amendments (CLIA)-USA to perform high complexity clinical laboratory testing.
The data analysis and interpretation as well as the preparation of Reports, is carried out by our partner laboratory - Datar Cancer Genetics Private Limited, Nasik, India. This laboratory is certified to be compliant with ISO 15189:2012, ISO 27001:2013 and ISO 9001:2015 and is also accredited by the College of American Pathologists (CAP) and Clinical Laboratory Improvement Amendments (CLIA).

Disclaimer

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Results of ICC (antigen expression on CTCs) may vary from that of primary tumor tissue and over time due to tumor heterogeneity and other biological processes. Further, certain conditions such as active inflammatory diseases, medications, exposure to radiation, UV induced sunburn etc. may interfere with accuracy of assay results. Other potential sources of error include, but are not limited to, sample contamination / degradation or pre-analytical deviations.

The Trublood test is performed pursuant to suspicion of malignancy, such as clinical features, imaging etc. Decisions on patient care and treatment must be based on the independent medical judgement of the treating physicians, taking into consideration all available and relevant information concerning the patient's condition, such as personal and family history, physician's examination as well as information from other pertinent diagnostic tests. A treating physician's decisions should not be based on a single test or solely on the information contained in this report.

Test interpretation has been done in line of the primarily suspected organ. As the ICC markers are expressed differently in

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different malignancies, any other malignancy than the suspected one cannot be ruled out.

This report should be read as a whole and used and acted upon only by a registered / licensed medical practitioner under the relevant law who is duly qualified to practice medicine.

This is not a prescription.

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End of Report

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Trublood - Prostate fulfills the requirements of the European Directive 98/79 EC for in vitro diagnostic medical devices and is registered as a CE-IVD by Datar Cancer Genetics EU Authorized Representative,

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Notes

1. Some or all of the processes / algorithms employed in Trublood may be the subject matter of national / international patents and are the sole property of Datar Cancer Genetics.
2. Trublood and CellWizard are trademarks owned by Datar Cancer Genetics and are the subject matter of intellectual property rights applications worldwide.

Important Note

This report should be interpreted and acted upon only by a duly qualified medical professional who is registered / licensed to practice medicine under the relevant law.

This report should always be read as a whole and reproduced if necessary, in its entirety.

- Please read the Disclaimer section carefully.

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