Promis Diagnostics
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CLIA#: 05D2185450 CAP#: 879466501

EarlyTect® Bladder Cancer Detection Test Report

Patient Information

Name: NameFirst NameLast
DOB: 1990.12.07
Gender: M
Medical Record Number: ##########
Address: 1 Post, Irvine, California, 92618

Specimen Information

Accession Number: BCTEST-003
Date Collected: 2023.12.04
Date Received: 2023.12.05
Report Date: 2023.12.05
Sample Type: Urine

Physician Information

Facility Name: Promis Dx
Provider Name: PROMIS DIAGNOSTICS, INC.
Address: 1 Post, Suite 100 - Suite 100 - Irvine - California

EarlyTect® Bladder Cancer Detection Test

Test	Results	Normal Reference Range
PENK DNA methylation	**Positive****	**Negative**

Result Interpretation:
*A negative result indicates a lower risk of bladder cancer or no bladder cancer. However, a negative EarlyTect® Bladder Cancer Detection (EarlyTect® BCD) test result does not guarantee absence of cancer. Patients with a negative EarlyTect® BCD test result should be advised to continue participating in a recommended bladder cancer screening program according to screening guidelines.

**A positive result indicates a higher probability of bladder cancer. A positive result is not confirmatory evidence for bladder cancer. Patients with a positive EarlyTect® BCD test result should be referred for diagnostic cystoscopy.

Test Description:
The EarlyTect® BCD is a proprietary in vitro genetic test designed to detect the presence of bladder cancer by analyzing urine DNA for patients through qualitative analysis of a single epigenetic biomarker gene DNA methylation (methylated PENK DNA). The EarlyTect® BCD is for use with a methylation-specific real-time PCR detection system coupled with linear target enrichment step (LTE-qMSP) after DNA extraction and bisulfite conversion. It detects both methylated PENK and an internal control gene.
This test confirmed that patients with hematuria can be diagnosed with 85.7% accuracy for all stages bladder cancer and 90% accuracy for Ta high grade and higher stages bladder cancer in clinical trials[1,2].

Limitation:
Improper specimen collection techniques, storage, or shipment protocols may cause unreliable results.
An absence of detection does not imply the absence of bladder cancer or does not exclude the possibility that the target sequence is present below the limit of detection. The EarlyTect® BCD report does not take into consideration patient history, drug-drug interactions, drug sensitivity, and/or allergies. It is the responsibility of the physician to determine appropriate drug and dosing choices based on all available data.

Disclaimer: This test is lab developed test and its performance characteristics determined by Promis Dx. This test has not been cleared or approved by the U.S. Food and Drug Administration (FDA). The FDA has determined that such clearance or approval is not necessary. This test is used for clinical purposes and should not be regarded as investigational or for research. The laboratory is regulated under the Clinical Laboratory Improvement Amendments (CLIA) of 1988 as qualified to perform high complexity clinical testing and is accredited by the College of American Pathologists (CAP).

Approved by: Safedin Beqaj, Ph. D., HCLD, CC (ABB)

Clinical Laboratory Improvements Amedments

CAP ACCREDITED
COLLEGE of AMERICAN PATHOLOGISTS

References: 1. Oh TJ, et al. J Mol Diagn. 2023, 2. Oh TJ, et al. BMC Cancer. 2022.

This report, associated with order #BCTEST-003, has been approved by the following reviewers:

Comment: None

Admin:

Electronically signed and dated on 2023.12.05 15:45
Dr. Bo Ram Bang

References: 1. Oh TJ, et al. J Mol Diagn. 2023, 2. Oh TJ, et al. BMC Cancer. 2022.