

LABORATORY REPORT

Example Client, XYZ123 1234 Warde Road Ann Arbor MI 48108 **EXAMPLE, REPORT W**

WX0000003827 M 07/08/1978 45 Y

Referral Testing

Collected: 08/31/2023 10:49 Received: 08/31/2023 10:49

<u>Test Name</u> <u>Result</u> <u>Flag Ref-Ranges</u> <u>Units</u> <u>Site</u>

Bladder Cancer, FISH (UroVysion)

Bladder Cancer, FISH See Below QCRL

Order ID: 23-379313

Specimen Type: Urine

Clinical Indication: ATYPICAL UROTHELIAL CELLS SUSPICIOUS FOR

RESULT:

POSITIVE RESULT FOR THE UROVYSION FISH ASSAY

INTERPRETATION:

An abnormal hybridization pattern was observed with thirty cells exhibiting numerical abnormalities of chromosomes 3, 7, 9, and 17. This result is indicative of bladder cancer according to the UroVysion Directional Insert (Abbott Molecular/Vysis).

Positive UroVysion results in the absence of other signs or symptoms of bladder cancer may be evidence of other urinary tract related cancers, e.g., ureter, urethra, renal, and/or prostate in males, and further patient follow-up is justified. If the test results are not consistent with the clinical findings, a consultation between a pathologist and the treating physician is warranted.

The Vysis UroVysion test was designed for use on voided urine specimens as an aid for the initial diagnosis of bladder carcinoma in patients with hematuria and subsequent monitoring for tumor recurrence in patients previously diagnosed with bladder cancer.

Please expect the results of any other concurrent study in a separate report.

REFERENCE for SENSITIVITY and SPECIFICITY:

Halling KC and Kipp BR. Bladder cancer detection using FISH (UroVysion assay). Adv Anat Pathol 2008;15:279-86.

NOMENCLATURE:

nuc ish(D3Z1x4,D7Z1x4,CDKN2Ax0-2,D17Z1x3-4)[30]

ASSAY INFORMATION:

Method: FISH Manual Analysis

Cells Counted: 30

LAB: L - LOW, H - HIGH, AB - ABNORMAL, C - CRITICAL, $\,$. - NOT TESTED

F231000021 WX0000003827 Printed D&T: 08/31/23 10:50 Ordered By: KAJAL SITWALA, MD, PhD WX00000000002365

Kajal V. Sitwala, MD, PhD - Medical Director Form: MM RL1 PAGE 1 OF 2



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Detection of >/=4 of the 25 cells showing gains for 2 or more chromosomes (3, 7 or 17) in the same cell, or >/=12 of the 25 cells having zero 9p21 signals is interpreted as a POSITIVE result.

Although the UroVysion test was designed to detect genetic changes associated with most bladder cancers, not all genetic changes can be detected by this test.

Morteza Hemmat, PhD, FACMG (800) NICHOLS-4307

Electronic Signature: 8/29/2023 3:33 PM

Test Performed at:

Quest Diagnostics Nichols Institute

33608 Ortega Highway

San Juan Capistrano, CA 92675-2042 I Maramica MD, PhD, MBA

Clinical Indication Atypical urothelial cells

suspicious for

Specimen type / Source URINE QCRL

Performing Site:

QCRL: QUEST DIAGNOSTICS REFERENCE LAB CAPISTRANO 33608 Ortega Highway San Juan Capistrano CA 92675

Reported Date: 2023.08.31 10:50 UROVQ