URINE CYTOLOGY & URO17™ REPORT

ACUPATH LABORATORIES, INC

Amended Report

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PHYSICIAN: DOCTOR, M.D.
PRACTICE NAME
ANY STREET
ANY CITY, STATE, ZIP
Acct # 0000-0000-00
☎ (XXX) XXX-XXXX
🖷 (XXX) XXX-XXXX

PATIENT: JOHN PATIENT **DOB: 11/01/1940**
ANY STREET
ANY CITY, STATE, ZIP
(XXX) XXX-XXXX
Acct#: XXXXXX
Age: 80
Sex: Male
Chart/A/C#XXXX

Client Comments: ICD:C67.9

URINE CYTOLOGY RESULTS (A)

- **DIAGNOSIS: HIGH POSITIVE FOR HIGH GRADE UROTHELIAL CARCINOMA.**

Notes: THIS IS AN AMENDED REPORT BASED ON ADDITIONAL REVIEW OF URO17.

URO17™ BIOMARKER RESULTS

- **POSITIVE**

Number of positive cells: 25

URO17™ SCORING CRITERIA

Diagnosis Categories	Number of stained urothelial cells
Negative	0 - 4
Low Positive	5 - 19
High Positive	≥ 20

GROSSING

Adequacy: Satisfactory For Evaluation.
Specimen Type: Urine, Voided
Gross Description: Rec'd 90ml of fixed yellow urine in Thin Prep vial. Prepared 1 Thin Prep slide. Performed 1 URO17.

Disclaimer:
Voided urine specimens with increased expression of Cytokeratin 17 have been identified as having or developing a bladder neoplasia (see references below). Specimen was tested using the Keratin 17 (K17) mouse monoclonal antibody KDX 1-1032A Anti-Keratin 17, with appropriate positive and negative controls as required by ASCO-CAP guidelines. Immunocytochemical slides were reviewed manually and scored in accordance with the following criteria: NEGATIVE: 0-4 cells with any URO17 expression: LOW POSITIVE: 5-19 urothelial cells with at least 2+ staining intensity, HIGH POSITIVE: ≥ 20 urothelial cells with at least 2+ staining intensity, NON-CONTRIBUTORY: no urothelial cells seen for evaluation.
Prior urothelial trauma or treatment for bladder cancer may complicate the result of URO17 test and cause potentially false-positive URO17 results. URO17 results should be utilized in conjunction with other known clinical risk factors to assess overall risk of urothelial carcinoma.
This test was developed and its performance characteristics determined by Acupath Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test is used for clinical purposes It should not be regarded as investigational or for research. This laboratory is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as qualified to perform high complexity testing.

References:
"Keratin 17 Is a Novel Cytologic Biomarker for Urothelial Carcinoma Diagnosis": Babu S, Kim N, Wu M, et al., 2021, Am J Clin Pathol, DOI: 10.1093/AJCP/AQAB050
"The role of URO17™ biomarker to enhance diagnosis of urothelial cancer in new hematuria patients - First European Data"; Vasdev N, Hampson A, Agarwal S, et al., 2021, BJUI Compass 2:1, p46-52
"Validation of a Novel Cytologic Biomarker for Urothelial Carcinoma": Babu et al., 2019, Bladder Cancer: Transforming the Field, AACR, Denver, CO.
"Keratin 17 is a sensitive and specific biomarker of urothelial neoplasia"; Babu et al., 2018, Modern Pathology 32(5): 717-724

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