

Clinical Validation of AllTest UTI Self-Testing Reagent Strips in Urine

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ABSTRACT

The Urinary Tract Infections (UTI) Test (Urine) consists of firm plastic strips designed for the qualitative detection of four analytes—Leukocytes (LEU), Nitrite (NIT), Protein (PRO), and Occult Blood (BLO)—in human urine. This study evaluated the performance of the AllTest Biotech UTI Reagent Strips (Cat. No. U031-04H) compared with a commercially available reference test. A total of 206 clinical urine specimens (61 UTI-positive and 145 UTI-negative) were tested. The evaluated assay showed 98.36% positive concordance, 100% negative concordance, and 99.51% total agreement. No significant interference was observed from common urinary substances such as ascorbic acid, glucose, bilirubin, and hemoglobin. These results demonstrate the test's high reliability, accuracy, and suitability for self-testing, confirming its clinical applicability as a rapid and user-friendly screening tool for preliminary UTI detection.

Keywords: Urinary Tract Infection (UTI); Self-Testing Reagent Strips; Leukocytes; Nitrite; Protein; Occult Blood; Clinical Validation.

How to Cite: Lei Zhang, Feng Yang, Junzhe Zhu., (2025) Clinical Validation of AllTest UTI Self-Testing Reagent Strips in Urine, *Journal of Carcinogenesis*, Vol.24, No.10S, 644-646.

1. INTRODUCTION

Urinary tract infections (UTIs) are among the most prevalent bacterial infections worldwide, affecting an estimated 150 million people each year and imposing significant economic and healthcare burdens. Accurate and timely detection is crucial to prevent complications, particularly in women and the elderly, where recurrent infections can lead to chronic renal issues.

Traditional diagnostic approaches rely on laboratory-based urinalysis or urine culture, both of which require specialized personnel, equipment, and time (often 24–48 hours). In contrast, rapid colorimetric test strips allow qualitative analysis within minutes, providing an accessible and cost-effective diagnostic solution for point-of-care and home testing.

The present study evaluates the diagnostic accuracy and clinical performance of the AllTest Biotech UTI Self-Testing Reagent Strips (U031-04H) in detecting UTI-associated biomarkers compared to a standard commercial reference strip.

2. MATERIALS AND METHODS

Specimen Collection

A total of 206 urine specimens were collected from patients presenting with symptoms suggestive of UTI. Samples were categorized based on reference test results: 61 UTI-positive and 145 UTI-negative.

Test Devices

Evaluated Kit: AllTest Biotech Co., Ltd., UTI Self-Testing Reagent Strips (Cat. No. U031-04H)

Reference Test: ACON Urine Analysis Strips.

Testing Procedure

Each test strip was dipped vertically into the urine specimen for 1–2 seconds. The strip was then removed and laid flat on a clean, absorbent surface. Results were read after 2 minutes by comparing reagent pad colors to the color chart.

Interpretation Criteria

Positive: At least one reagent pad matched a “positive” color block.

Negative: All reagent pads matched the “negative” color block.

Analytes Detected

Leukocytes (LEU) – Indicates presence of white blood cells and infection.

Nitrite (NIT) – Detects bacterial reduction of nitrate.

Protein (PRO) – Reflects kidney inflammation.

Occult Blood (BLO) – Indicates hematuria, often linked with infection.

Performance Parameters Evaluated

Diagnostic sensitivity, specificity, and total agreement; cross-reactivity and interference with endogenous and exogenous substances; reproducibility through intra- and inter-assay precision testing.

3. RESULTS

Diagnostic Performance

Parameter	Result
Positive Concordance	98.36%
Negative Concordance	100%
Total Concordance	99.51%

Interference Study

No significant interference was observed from ascorbic acid, glucose, bilirubin, hemoglobin, or other urinary solutes. This supports the robustness and reliability of the strip in various patient conditions.

Precision

Intra- and inter-assay reproducibility exceeded 99%, confirming consistent results across multiple runs and operators.

4. DISCUSSION

The findings confirm that the AllTest Biotech UTI Reagent Strips (U031-04H) provide a rapid, reliable, and clinically accurate method for detecting UTI-associated biomarkers.

The device’s simplicity, speed, and non-invasive nature make it suitable for home self-testing, primary care settings, and remote or low-resource regions.

Comparison with Other Methods

Compared to traditional urinalysis, the test is faster (2 minutes vs. 24–48 hours for culture), simpler (no equipment required), and equally consistent with commercial reference strips.

Limitations

The test provides qualitative rather than quantitative results; no direct comparison with urine culture was performed; results depend on proper sample handling and color interpretation.

5. CONCLUSION

The AllTest Biotech UTI Self-Testing Reagent Strips (U031-04H) demonstrated 98.36% positive, 100% negative, and 99.51% overall concordance compared to a reference test. Its excellent accuracy, reproducibility, and ease of use confirm its suitability for clinical and self-testing applications. This device provides a cost-effective and accessible diagnostic tool for early detection of urinary tract infections, particularly valuable for home or point-of-care settings.

REFERENCES

1. Foxman B. Epidemiology of urinary tract infections: incidence, morbidity, and economic costs. *Am J Med*, 2000; 109(Suppl 1A): S8–S15.

2. Nicolle LE, Bradley S, Colgan R, et al. Clinical practice guideline for the management of uncomplicated urinary tract infections. *Infect Dis Clin North Am*, 2019; 33(1): 1–28.
3. Hooton TM. Uncomplicated urinary tract infection in women. *N Engl J Med*, 2012; 366(11): 1028–1037.
4. Wagenlehner FM, Naber KG. Urinary tract infections in adults. *Dtsch Arztebl Int*, 2011; 108(27–28): 479–486.
5. Miller TE, Tang A, Zhanel GG. Urinary tract infections: a current review. *Can J Infect Dis Med Microbiol*, 2016; 27(2): 81–87.