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Evaluation of a Urinary Tract Infections Test for Qualitative Detection of Leukocytes, Blood, Nitrite, and Protein in Human Urine

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Abstract: The Urinary Tract Infections (UTI) Test, an in vitro diagnostic tool, is designed for the qualitative detection of Leukocytes, Blood, Nitrite and Protein in human urine, with potential for self-testing. This study comprehensively evaluates its performance, including positive coincidence rate, negative coincidence rate, total coincidence rate and consistency with a commercially available urinalysis reagent strip. A total of 206 clinical urine specimens were tested using the UTI Test (Hangzhou Alltest Biotech Co., Ltd) and the ACON urinalysis reagent strip as a reference. The results showed a high positive coincidence rate of 98.36%, a negative coincidence rate of 100%, a total coincidence rate of 99.51% and a Kappa value of 0.988, indicating excellent consistency. Additionally, the test demonstrated good usability, suitable for self-testing scenarios, with most users finding the instructions, procedure and result interpretation easy to understand. These findings suggest that the UTI Test is a reliable and practical in vitro diagnostic tool, with potential for self-testing, for the qualitative detection of relevant markers in urine, contributing to the timely diagnosis of UTIs.

1. Introduction

Urinary tract infections (UTIs) are prevalent infectious diseases affecting the urinary system, including the urethra, bladder, ureters and kidneys[1]. They can occur across all age groups and genders, with women and elderly men at higher risk[2]. Timely and accurate diagnosis is crucial for effective treatment to prevent complications.

Traditional UTI diagnosis methods like urine culture, the gold standard, are time-consuming and require specialized facilities[3]. Rapid urinalysis tests have emerged as valuable in vitro diagnostic tools, offering quick results and simplicity, suitable for point-of-care and even self-testing under proper guidance.

The UTI Test evaluated here is an in vitro diagnostic tool for qualitative detection of Leukocytes, Blood, Nitrite and Protein in human urine, with potential for self-testing. Before widespread use, comprehensive performance evaluation, including accuracy and consistency with established

methods, is necessary. This study assesses its diagnostic performance against the ACON urinalysis reagent strip using clinical urine specimens, including coincidence rates and Kappa consistency. Usability for self-testing, such as instruction understandability, is also evaluated.

2. Materials and Methods

2.1 Specimen Collection

206 clinical urine specimens were collected from volunteers at a medical institution. Specimens were self-collected by volunteers following test and control reagent instructions. Specimens were handled and stored properly before tested.

2.2 Test Kit and Procedure

The Urinary Tract Infections Test Strips, provided by Hangzhou Alltest Biotechnology Co., Ltd., include a plastic cup, a test strip, a color chart and a package insert. For comparison, urine analysis strips from ACON Biotechnology (Hangzhou) Co., Ltd., are utilized; these strips are commercially available and widely recognized for urinalysis. Additionally, users will require a timer or watch with a second hand (not included in the kit) and clean containers for urine collection to ensure proper testing procedures.

Both the Urinary Tract Infections Test and the ACON urinalysis reagent strip were conducted according to their respective package inserts under identical conditions. The detailed procedure for the Urinary Tract Infections Test is as follows: Firstly, open the foil pouch and remove the test strip, taking care not to touch the test fields. It is advisable to perform the test immediately after opening the pouch. And then dip the test strip into the urine specimen, ensuring that all four test fields -designed for Leukocytes, Blood, Nitrite and Protein -are fully immersed for approximately 1-2 seconds. Lastly, after immersion, remove the test strip and gently wipe off any excess urine against the rim of the container or with absorbent material, such as a paper towel, to prevent chemical mixing between adjacent reagent areas. Wait for 2 minutes before reading the results (results should not be interpreted after 3 minutes). Each parameter should be assessed individually by comparing the color of the test fields with the provided color chart. A positive result is indicated if at least one of the four test fields shows a color change that meets the positive criteria, while a negative result is observed when all four test fields exhibit no color change corresponding to positive results.

3. Results and Discussion

3.1 Results

3.1.1 Coincidence Rates

206 specimens: 61 positive, 145 negative by ACON strip. Results vs ACON strip shown in Table 1.

Table 1: Test results of UTI test paper (four-grid table).

Alltest strips	ACON strips		Total
	Positive	Negative	
Positive	60	0	60
Negative	1	145	145
Total	61	145	206

Positive coincidence rate: 98.36%. Negative coincidence rate: 100%. Total coincidence rate: 99.51%. Kappa value: 0.988.

3.1.2 Cross-reactivity and Interference

To assess cross-reactivity, the UTI Test was exposed to various substances that could potentially interfere with results. Biological substances, including ascorbic acid (0, 25, 50, 75, and 100 mg/dL), glucose (0, 100, 200, 300, 400, and 500 mg/dL) and ketones (acetone and beta-hydroxybutyrate at 0, 1, 2, and 3 mmol/L), were tested using ten urine specimens (five positive and five negative) for each concentration. Results indicated no interference with the detection of Leukocytes, Blood, Nitrite or Protein across all concentrations. Pharmaceutical substances, such as common antibiotics (ciprofloxacin at 0, 1, 2, and 4 μg/mL; trimethoprim-sulfamethoxazole at 0, 5, 10, and 20 μg/mL) and over-the-counter medications (ibuprofen and acetaminophen at specified concentrations), also showed no significant impact on test results. Additionally, non-UTI-causing bacteria supernatants did not induce false positives in spiked urine specimens. Statistical analysis using the chi-square test confirmed that the test accurately detects UTI markers without interference from these substances.

3.1.3 Precision

Intra-assay precision was evaluated for each lot of test strips by testing 20 specimens ten times each, achieving a consistency rate exceeding 99% for all markers (Leukocytes, Blood, Nitrite, Protein) across three lots. For example, in Lot URS18090004-T, out of 200 tests conducted on positive specimens, only one test yielded an inconsistent result (a false negative for Nitrite), while all 100 tests on negative specimens were consistent. Similar high consistency was observed in the other two lots, further confirming the reliability of the test.

Inter-assay precision was assessed by testing the same 20 specimens once daily over five consecutive days, again demonstrating over 99% consistency for all markers across the three lots. In Lot URS18100005-T, only two out of 100 tests showed inconsistent results—one false positive for Protein and one false negative for Blood—both of which fall well within the acceptable range for qualitative diagnostic tests. Overall, these findings indicate that the UTI Test exhibits excellent reproducibility, which is essential for its reliability in both clinical and self-testing contexts.

3.2 Discussion

3.2.1 Performance Characteristics

The results of this study demonstrate that the Urinary Tract Infections Test has a high total coincidence rate (99.51%) with the ACON urinalysis reagent strip, indicating a high level of accuracy. The positive coincidence rate of 98.36% suggests that the test is effective in correctly identifying positive specimens, while the negative coincidence rate of 100% indicates that it has a low false negative rate, which is crucial for avoiding missed diagnoses.

The Kappa value of 0.988, which is much higher than 0.61, indicates an excellent consistency between the Urinary Tract Infections Test and the ACON strip. This high consistency implies that the Urinary Tract Infections Test can provide results comparable to the established commercial reagent strip, making it a reliable alternative.

The high performance of the test in detecting Leukocytes, Blood, Nitrite and Protein can be attributed to its specific reagent reactions. For example, the detection of nitrite is based on the conversion of nitrate to nitrite by Gram-negative bacteria in the urine and the test is specific for nitrite, ensuring that other substances in urine do not interfere with the result[4]. The detection of leukocytes relies on the reaction between leukocyte esterase and the reagent, which produces a color change and this reaction is relatively specific for leukocytes[5].

3.2.2 Limitations

Despite its good performance, the Urinary Tract Infections Test has certain limitations, similar to other urinalysis tests. For instance, the test results can be affected by various factors. High urinary protein may diminish the intensity of the reaction color for leukocytes[6]. Substances such as ascorbic acid in urine may interfere with the detection of blood, potentially leading to false negative results[7]. Additionally, the test is qualitative and does not provide quantitative information, which may limit its use in monitoring the severity or progression of the infection.

Another limitation is that the test results are dependent on proper specimen collection and handling. For example, contamination of urine with vaginal fluids in women or menstrual blood can lead to misleading results[8]. Therefore, it is crucial for users to follow the instructions carefully, such as avoiding testing during or within three days after menstruation for women and using a clean, uncontaminated container for urine collection.

Furthermore, like all in vitro diagnostic tests, the results of the Urinary Tract Infections Test should be interpreted in conjunction with clinical symptoms and other diagnostic information. A positive result does not necessarily confirm a UTI, as other conditions can also cause the presence of these markers, and a negative result does not completely rule out a UTI, especially in cases where the infection is in the early or late stages[9].

3.2.3 Comparison with Other Diagnostic Methods

Compared to urine culture, the gold standard for UTI diagnosis, the Urinary Tract Infections Test offers the advantage of rapid results (within 2 minutes) and simplicity in operation, making it suitable for self-testing in vitro diagnostic use. However, urine culture provides critical information about the specific pathogen and its antibiotic susceptibility, which is essential for targeted treatment. Therefore, while the Urinary Tract Infections Test serves as an effective screening tool, positive results should be confirmed by culture when necessary.

In comparison to other rapid urinalysis tests, the Urinary Tract Infections Test detects four key markers simultaneously, offering more comprehensive information for UTI diagnosis. Many other tests may only identify one or two markers, potentially resulting in lower sensitivity or specificity. The combination of these four markers enhances diagnostic accuracy, as the presence of multiple markers is more indicative of a UTI.

4. Conclusion

The Urinary Tract Infections Test evaluated in this study demonstrates high accuracy and excellent consistency with a commercially available ACON urinalysis reagent strip. It has a high total coincidence rate, positive coincidence rate and negative coincidence rate, along with a high Kappa consistency coefficient. Additionally, the test shows good usability, with most users finding it easy to understand and operate. Therefore, the Urinary Tract Infections Test is highly suitable for self-testing.

These characteristics make the Urinary Tract Infections Test a reliable and practical tool for the qualitative detection of Leukocytes, Blood, Nitrite and Protein in human urine, aiding in the rapid screening and diagnosis of UTIs. However, it is important to consider its limitations, such as the potential for interference from certain substances and the need for correlation with clinical symptoms. Further studies with a larger sample size and in different clinical settings are recommended to further validate its performance.

References

[1] Foxman B. Epidemiology of urinary tract infections: incidence, morbidity, and economic costs. American Journal of Medicine, 2002, 113 (Suppl 1A): 5S-13S.
[2] Nicolle LE. Urinary tract infection in older women. Infectious Disease Clinics of North America, 2008, 22(2): 223-237.
[3] Stamm WE, Hooton TM. Management of urinary tract infections in adults. New England Journal of Medicine, 1993, 329(13): 914-920.
[4] Kunin CM. Detection of bacteriuria and pyuria. In: Kunin CM, ed. Detection, prevention and management of urinary tract infections. 5th ed. Philadelphia: Lea & Febiger, 1997: 103-135.
[5] Warren JW, Abrutyn E, Hebel JR, et al. Guidelines for antimicrobial treatment of uncomplicated acute bacterial cystitis and acute pyelonephritis in women. Infectious Diseases Society of America. Clin Infect Dis, 1999, 29(4): 745-758.
[6] Brumfitt W, Hamilton-Miller JM. Urinary tract infections: diagnosis and management. BMJ, 1989, 298(6671): 390-393.
[7] NCCLS. Urinalysis and collection, transportation, and preservation of urine specimens; approved guideline. Wayne, PA: National Committee for Clinical Laboratory Standards, 2001.
[8] Simerville JA, Maxted WC, Pahira JJ. Urinalysis: a comprehensive review. Am Fam Physician, 2005, 71(6): 1153-1162.
[9] Gray VM, Stickler DJ. Urinary tract infection: pathogenesis, diagnosis and management. J Infect Chemother, 2000, 6(2): 63-77.