accutest®

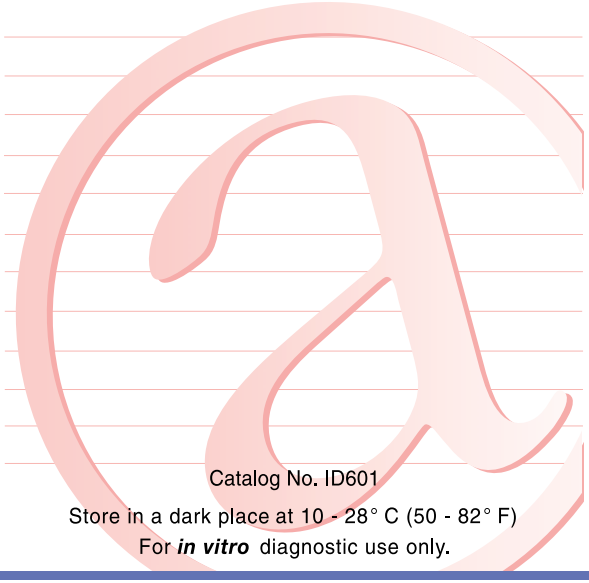
URISCREEN 20

TEST KIT FOR 20 DETERMINATIONS

RAPID UTI SCREEN

TEST FOR BACTERIURIA AND PRESENCE OF SOMATIC CELLS IN URINE

INSTRUCTION MANUAL



Catalog No. ID601

Store in a dark place at 10 - 28° C (50 - 82° F)

For ***in vitro*** diagnostic use only.

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INTENDED USE

URISCREEN is a rapid screening test for UTI. The test is primarily intended for the screening of asymptomatic populations (e.g., routine testing in schools, industrial plants, institutions, hospitals, clinics, physicians' offices, etc.) for significant bacteriuria, hematuria, pyuria, and the presence of other somatic cells in urine.

A POSITIVE RESULT INDICATES THAT THE URINE REQUIRES FURTHER LABORATORY EXAMINATION FOR MORE DETAILED DIAGNOSIS.

PRECAUTIONS AND WARNINGS

1. This kit contains a 10% hydrogen peroxide (H_2O_2) solution and a colored reagent powder which stains and may be irritating. Do not heat or mix with flammable substances. Avoid contact with eyes, skin and clothing. In case of such contact, flush immediately with a large volume of water.
2. Urine specimens should be treated as potentially infectious material and treated as such.
3. The reagents in this kit have been standardized as a unit. No reagents should be used which are **outdated**, bear a **different lot number** from that imprinted on this kit, or are manufactured by **another manufacturer**.
4. The reagents included in this kit are for ***in vitro*** **diagnostic use only**.

INTRODUCTION

Urinary tract infections are considered to be among the most frequently occurring infectious diseases.

Surveys have demonstrated that approximately 80% of the urine specimens cultured in clinical microbiology laboratories are either negative or

contain no significant bacteriuria. The classical screening methods for bacterial contamination of urine are still based on bacteriological culture plating, which generally requires a minimum of 24 hours, and is usually expensive.

The obvious need for faster and less costly screening methods for bacteriuria and other urinary tract anomalies – especially among asymptomatic populations – has led to the development of alternative techniques. Most are based on sensitive and specific staining procedures for various bacterial and somatic cell components, or on detecting the presence of intracellular molecules such as adenosine triphosphate and certain enzymes not usually present in healthy urine[1-6].

Catalase has been found to be present in many eukaryotic and prokaryotic cells[7-9]. In infected urine, it has been found in most bacteria that attack the urinary tract, as well as in inflammatory exudate cells[9-11]. It is also present in high concentrations in kidney cells[17].

Urine which is normal, clean and healthy has no significant catalase activity[10,11,18]. When detected by the **URISCREEN** test, catalase activity is indicative of significant bacteriuria ($>5 \times 10^4$ CFU/ml) and/or an abnormally high number of somatic cells (>10 per high power field), typically associated with infection, damage or other urinary tract pathology.

It is well recognized that the evaluation of asymptomatic urine specimens for infection should include **both bacteriuria and pyuria**, since in many cases results of high bacterial counts were found to be indicative **only when accompanied by a test for pyuria**[12-15]. This rationale has also led other manufacturers to combine screening tests for bacteria (e.g. nitrite test) with tests for pyuria (e.g. leukocyte esterase test).

The **URISCREEN** test combines the detection of both bacteriuria and the presence of somatic cells in urine, in a single test which is extremely simple to perform, requires no equipment, is inexpensive, and **can be completed *and evaluated* in about a minute**.

PRINCIPLES OF THE TEST

In the first step, the urine specimen is mixed with a test reagent powder which enables catalase detection. This step is fast, taking only a few seconds to complete.

In the second step, a small amount of hydrogen peroxide solution is added to the contents of the tube and mixed. The quantity of the resulting foam indicates the presence and relative level of catalase originating from bacterial and/or somatic cells in the urine. Lack of foam indicates negative test results.

KIT CONTENTS

- ☐ 20 stoppered test tubes, with the test reagent powder. It is stable until the expiration date of the kit, providing the test tubes are stored unopened at room temperature.
- ☐ One dropper bottle containing 10 ml of 10% hydrogen peroxide (H_2O_2) solution. It is stable until the expiration date of the kit, providing it is stored in the dark at room temperature.
- ☐ 20 disposable 2 ml pipettes
- ☐ Instruction manual

MATERIALS NEEDED BUT NOT SUPPLIED

- ☐ Negative control solution and impregnated discs for reconstruction of a positive control, (Catalog No. 104-01), available from Jant Pharmacal Corporation.

QUALITY CONTROL PROCEDURE

A positive and negative controls must be run once upon opening a new lot.

Instructions for performing these controls are provided with the reagents needed (negative control solution and impregnated disks).

NOTE: If the positive control does not yield an appropriate result, repeat the test, preferably with an impregnated disk from a new lot. If a proper result is not obtained, the test kit should not be used.

COLLECTION AND PREPARATION OF SPECIMENS

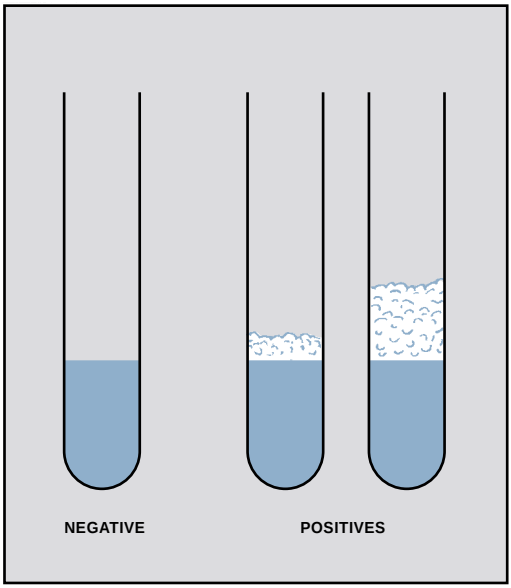
Collect midstream urine in a clean container. Test as soon as possible. If test cannot be performed within one hour after collection, the sample may be stored at 4 °C (39 °F) for not more than four hours.

TEST PROCEDURE

1. Transfer 1.5 – 2 ml. of the urine to be tested into a provided test tube containing **URISCREEN** Reagent Powder. Use one test tube for each urine sample. Repeat this step for every specimen to be tested up to a maximum of 20 tubes "in one operation".
2. Add four drops of **URISCREEN** 10% Hydrogen Peroxide Solution to each test tube. Mix gently, in order not to produce foam, for five seconds.
3. Watch for foam formation and monitor the results for 1-2 minutes after initiation of step 2. If the test is positive, foam will be formed on the surface of the liquid. Observe the foam, then refer to the Result Interpretation (Figure 1).

INTERPRETATION OF RESULTS

Figure 1:



Positive Results

Foam is generated at least to an extent sufficient to form a complete and continuous ring or layer on the surface of the liquid along the test tube walls.

The formation of foam indicates the presence of catalase in the urine (refer to Figure 1). A positive result indicates UTI. The urine of that patient should be further examined using more detailed procedures.

Negative Results

Either no foam whatsoever is generated, or the ring of foam remains incomplete at the end of two minutes.

LIMITATIONS OF THE TEST

1. The **URISCREEN** test does not detect catalase–negative organisms, such as certain species of Streptococcus which occur in approximately 2% of all specimens screened, and 5 – 10% of those demonstrating positive results. However, about half of these species are detectable by the **URISCREEN** test **via the pyuria** which was found to accompany about 50% of these infections.
2. As with all **screening** tests, definitive diagnostic or therapeutic decisions should not be based on any single method or result.
3. Specimens should be well mixed to ensure that a representative sample is tested.
4. A positive result indicates that the patient's urine should be subjected to more detailed examination.

PERFORMANCE CHARACTERISTICS

In a comparative study conducted during a six-month period, 2,961 urine specimens from asymptomatic populations were randomly collected. Bacterial counts were determined by plating on MacConkey and blood agar plates; somatic cells were counted microscopically. In parallel, the specimens were also tested by the **URISCREEN** test; the results are presented in Table 1.

Table 1:

Bacterial Counts (CFU/ml)	Somatic Cells	Results With URISCREEN	
		POSITIVE	NEGATIVE
<10,000	–	347	1426
	+	381	21
10,000 – 50,000	–	66	34
	+	70	10
>50,000	–	173	38
	+	378	17

Sensitivity, specificity and negative predictive value were calculated at two cutoff levels of bacterial counts: >10,000 CFU/ml and >50,000 CFU/ml.

A. Specimens with significant pyuria, hematuria, or other somatic cells (>10 cells per high power field), as determined by microscopic counting, were considered as true positives even if bacterial counting showed less than 10,000 CFU/ml. The specimens containing <10,000 or <50,000 CFU/ml (depending on the cutoff level considered) without somatic cells were considered true negatives.

1. For bacteriuria cutoff level at >10,000 CFU/ml:
   Sensitivity = 90%
   Specificity = 80%
   Negative Predictive Value = 92%
2. For bacteriuria cutoff level at >50,000 CFU/ml:
   Sensitivity = 92%
   Specificity = 78%
   Negative Predictive Value = 94.5%

B. Considering that evaluation of urine specimens for UTI should include both bacteriuria and pyuria[12-15], only those specimens that contained >10,000 CFU/ml and >10 somatic cells per high power field were considered as true positives.

Sensitivity and negative predictive value are:

Sensitivity = 94%
Negative Predictive Value = 98%

In another comparative study, 976 urine specimens were collected from asymptomatic populations. Bacterial counts were determined by counting on MacConkey and Cled agar plates on dip slides. Somatic cells were counted microscopically.

Table 2 depicts the results, compared with those obtained by the **URISCREEN** test.

Table 2

Bacterial Counts (CFU/ml)	Somatic Cells	Results With URISCREEN	
		POSITIVE	NEGATIVE
<50,000	–	95	462
	+	236	8
>50,000	+ and –	160	15

In calculating sensitivity, specificity and negative predictive value, specimens were considered negative if they showed less than 5×10^4 CFU/ml and/or less than 10 somatic cells per high power field.

The following results were obtained:

Sensitivity	= 94%
Specificity	= 83%
Negative Predictive Value	= 95%

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