

ACCUTEST® URISCREEN™ VET Rapid UTI Screen

Rapid Urinary Tract Screen to aid in assessing urinary tract health and detecting urinary tract infection in dogs and cats

Instruction Manual

Test kit for 20 determinations
(Catalog no. ID608VET)

For In Vitro Diagnostic Use

For veterinary use only

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

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Intended Use

ACCUTEST® URISCREEN™ is a rapid screening test to aid in assessing urinary tract health and detecting urinary tract infection (UTI) in dogs and cats. This test screens for bacteriuria, hematuria, pyuria and the presence of other somatic cells.

A POSITIVE RESULT INDICATES THAT URINE REQUIRES FURTHER DIAGNOSTIC EVALUATION.

Introduction

Assessing urinary tract health is an important part of providing quality veterinary medical care. Diagnosis of urinary tract infection in otherwise healthy dogs and cats, exhibiting typical signs with bacteriuria is usually straightforward. However, screening apparently healthy individuals or animals with chronic disease can be challenging. Urine test limitations and administration of certain medications also increase the difficulty of making the correct diagnosis. The ACCUTEST® URISCREEN™ aids in the assessment of UT health and the detection of UTI in dogs and cats with no sample preparation and no need for additional equipment.

Test Limitations:

Urine dipsticks are an easy, inexpensive tool to identify proteinuria and hematuria, but do not reliably detect pyuria or bacteriuria ⁽¹⁾. While microscopic examination of urine allows visualization of microbes and somatic cells, it requires time and training for sample preparation and interpretation ⁽²⁾. Quantitative urine culture is useful for confirmation of a urinary tract infection, but is expensive and results are not available for 24 to 48 hours ⁽²⁾.

Assessing Animals with Chronic Disease or Receiving Certain Medications:

Assessing the urinary tract health of animals with chronic disease or receiving certain medications can be challenging as these animals may not mount an appropriate inflammatory response to infection and can experience asymptomatic bacteriuria ⁽³⁾. Chronic diseases, which may put an animal at risk for asymptomatic bacteriuria, include retroviral infection (i.e., Feline Leukemia Virus), endocrinopathy (i.e., diabetes mellitus, hyperadrenocorticism, hyperthyroidism) and organ disease (i.e., chronic kidney disease) ^(4,5,6). Medications (i.e., cyclosporine, glucocorticoids) can compromise immune function ⁽⁷⁾. Urinalysis in animals with asymptomatic bacteriuria may be negative for protein, white blood cells and red blood cells in spite of infection.

Animals with chronic disease or receiving certain medications may produce dilute urine, making the identification of bacteria on microscopic examination more difficult ⁽⁸⁾ and reducing the sensitivity of the urine sediment exam. Polyuria, polydipsia (PU/PD) and dilute urine frequently characterize diseases such as diabetes mellitus, hyperadrenocorticism and chronic kidney disease. Medications such as glucocorticoids often cause dilute urine by inducing PU/PD. Pet owners may confuse polyuria and polydipsia associated with these diseases with the clinical signs of urinary tract infection (i.e. stranguria, dysuria) further adding to the difficulty of assessing urinary tract health.

The ACCUTEST® URISCREEN™ is a rapid catalase based urine- screening test to aid in assessing urinary tract health and detecting UTI in dogs and cats. Catalase has been found to be present in many eukaryotic and prokaryotic cells ^(9,10). In infected urine, it has been found in most bacteria that colonize the urinary tract, as well as in inflammatory cells ^(10,11). It is also present in high concentrations in kidney cells ⁽¹³⁾.

Normal, healthy urine has no significant catalase activity ^(11,12,14). When detected by the ACCUTEST® URISCREEN™, catalase activity is indicative of significant bacteriuria (>5 x10⁴ 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 ⁽¹⁵⁾. ACCUTEST® URISCREEN™ is simple to perform, requires no additional equipment and can be completed in one to two minutes.

Principle of the Test

In the first step, urine is mixed with test reagent powder which enables catalase detection. In the second step, a small amount of hydrogen peroxide solution is added to the contents of the tube and mixed. 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 a negative test result.

Kit Contents

- 20 stoppered test tubes, containing 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 (H₂O₂) 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 Required But Not Supplied

- Negative control solution and impregnated discs for reconstitution of a positive control, (Catalog No. ID104-01, available from Jant Pharmacal Corporation).

Quality Control Procedure

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

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

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.*

Precautions and Warnings

1. This kit contains a 10% hydrogen peroxide (H₂O₂) 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.
3. The reagents in this kit have been standardized as a unit. No reagents should be used which are **outdated**, bare 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**.

Collection and Preparation of Specimens

Cystocentesis is considered the preferred method of urine collection for most tests⁽²⁾. Catheterization is acceptable but may require sedation. Free-catch collection should be avoided and is generally considered an unacceptable method for collecting urine for diagnosing urinary tract infection in dogs and cats. Sample collection method must be considered, when interpreting test results.

Test urine as soon as possible. If the 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. After refrigeration, allow urine to reach room temperature and test immediately.

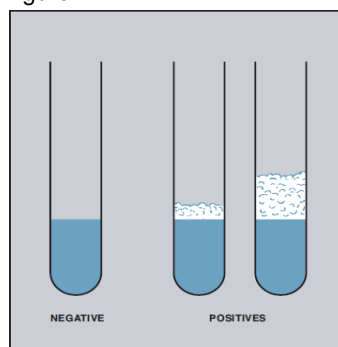
Test Procedure

1. Transfer 1.5 – 2 ml of urine into ACCUTEST® URISCREEN™ test tube containing Reagent Powder. Use one test tube for each urine sample.
2. Add four drops of ACCUTEST® URISCREEN™ 10% Hydrogen Peroxide Solution to each test tube*. Mix gently for five seconds. Avoid excessive agitation, as this may result in bubble formation, which could confuse test interpretation.
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 form on the surface of the liquid. Observe the foam, and then refer to the Result Interpretation (Figure 1).

*Do NOT recap test after adding peroxide solution.

Interpretation of Results

Figure 1



NEGATIVE

POSITIVE

Positive Results

Foam is generated and forms 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). The urine of the patient should be further examined using alternate 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 ACCUTEST® URISCREEN™ test does not detect catalase – negative organisms, such as certain species of *Streptococcus* and *Enterococcus*.
2. A positive ACCUTEST® URISCREEN™ test does not differentiate between the presence of bacteria, WBC, RBC and other somatic cells.
3. Urine should be well mixed prior to sampling 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

An independent study was performed at a veterinary teaching hospital, comparing ACCUTEST® URISCREEN™ to urine sediment examination. Urine culture was used as the gold standard. These results were reported in the Journal of Veterinary Internal Medicine ⁽¹⁶⁾.

165 urine samples were evaluated for 141 dogs (8 intact females, 73 spayed females, 10 intact males, 50 castrated males) and 19 cats (8 spayed females and 11 castrated males). One cat and four dogs were evaluated multiple times on separate occasions. Median age of dogs was 9 years (range: 0.5 to 15 years) and median age of cats was 12 years (range: 4 to 17 years).

Each sample was tested by three methods: 1. complete urinalysis including urine specific gravity, dipstick and microscopic examination 2. ACCUTEST® URISCREEN™, and 3. quantitative urine culture per acceptable lab procedures and test instructions.

Pyuria was defined as ≥ 3 leukocytes / hpf (40X). Microscopic hematuria was defined as ≥ 10 red blood cells /hpf (40X). Bacteriuria was defined by the presence of any identifiable bacteria on microscopic examination of either a wet mount or dried, stained smear. Urine culture was considered positive, if culture grew ≥ 1000 CFU/mL of 1 bacterial species.

Sensitivities and specificities, as well as their respective 95% confidence interval (CI) were calculated for ACCUTEST® URISCREEN™ and for microscopic examination, using culture results as the gold standard. Likelihood ratios of positive and negative test results were also calculated.

The results are as follows:

Screening Test (n=165)	Sensitivity % (CI)	Specificity % (CI)	LR+*	LR-**
URISCREEN	89 (71-97)	71 (63-78)	3	0.15
Abnormal Sediment Exam	78 (58-91)	90 (84-95)	7.8	0.24
URISCREEN and abnormal sediment exam	93 (76-100)	70 (61-77)	3.1	0.1

*Likelihood ratio of positive test result abbreviated as LR+

** Likelihood ratio of negative test result abbreviated as LR-

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