

ACCUTEST[®] URISCREEN[™] QUALITY CONTROL KIT

FOR *IN VITRO* DIAGNOSTIC USE

Catalog No. 104-01U

INTENDED USE

Negative and Positive Controls for the ACCUTEST[®] URISCREEN[™] Rapid UTI Screen Test. For *In Vitro* Diagnostic Use.

PRECAUTIONS AND WARNINGS

1. The kit contains discs impregnated with *Staphylococcus epidermis*. These bacteria are not considered primary pathogens to normal individuals. Nevertheless, the discs should be treated with the appropriate precautions.
2. The Negative Control Solution contains citric acid and is slightly acidic. Avoid contact with eyes. In case of such contact, flush immediately with a large volume of water.
3. A new unopened vial of the Negative Control Solution should be used in each test. Open the vial just before use.
4. The reagents included in this kit are for *In Vitro* Diagnostic Use.

TEST PROCEDURE

1. Transfer 1.5 - 2ml of the Negative Control Solution to two URISCREEN test tubes containing the Reagent powder. Label one tube "negative control".
2. Using forceps, transfer one of the impregnated discs into the other test tube. Label this tube "positive control".
3. Add 4 drops of URISCREEN 10% Hydrogen Peroxide Solution to each test tube and mix gently (in order not to produce foam) for 10 seconds, until the solution turns blue and most of the reagent has dissolved.
4. Observe foam formation 2 minutes after the addition of the Hydrogen Peroxide Solution.

INTERPRETATION OF RESULTS

Positive Control

A positive result is indicated by the generation of foam 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.

Negative Control

No foam is formed.

REMARKS

1. If the positive and negative controls do not yield an appropriate result, repeat the test.
2. If a proper result is not obtained in the repeat test, the tested URISCREEN kit should not be used.

SUMMARY AND EXPLANATION

The Negative Control Solution which substitutes for normal urine does not generate foam when testing by the URISCREEN test, thus indicating a negative result.

The Positive Control is a disc impregnated with bacteria (containing catalase). When a disc is used in the URISCREEN test, foam is generated, thus indicating a positive result.

KIT CONTENTS

- Five vials, each containing 5ml of Negative Control Solution.
- One vial with 6 impregnated discs.

STORAGE AND SHELF LIFE OF REAGENTS

All the materials supplied should be stored at 2°C - 8°C (36°F - 46°F). If kept at 2°C -8°C the test reagents are

stable until the expiry date indicated on the kit pack. Do not use the kit components beyond their expiration dates. Exposure of kit components to ambient temperature for a few hours will not cause damage to the reagents.

Do not expose reagents to strong light. Do not freeze the reagents.

Manufactured for:

JANT PHARMACAL CORPORATION

Encino, California 91436', USA

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2