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## Shiga Toxins 1 and 2 Rapid Test Strip

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*Cat. No.:DTS991*

*Pkg.Size:30T*

### Intended use

Detects all Shiga toxin-producing E. coli and differentiates between toxins 1 and 2 for optimal patient management while complying with CDC recommendations.

### General Description

Shiga toxins are a family of related toxins with two major groups, Stx1 and Stx2, whose genes are considered to be part of the genome of lambdoid prophages. The toxins are named for Kiyoshi Shiga, who first described the bacterial origin of dysentery caused by Shigella dysenteriae. The most common sources for Shiga toxin are the bacteria S. dysenteriae and the Shigatoxigenic group of Escherichia coli (STEC), which includes serotypes O157:H7, O104:H4, and other enterohemorrhagic E. coli (EHEC).

### Principle Of The Test

Immunochromatographic rapid assay

### Storage

Refrigerated, Shelf Life from date of manufacture is 12 Months

### Specimen Type

Human Stool

### Broth Enrichment

- 1.Gently mix unpreserved specimen.
- 2.Using a pipettor or transfer pipette (not supplied with the kit), add 50  $\mu$ L\* of specimen to a culture tube containing 8 mL of GN broth or 5 mL of MacConkey broth.
- 3.Incubate inoculated broth with caps loose at 35-39°C for 16-24 hours.

### Assay Steps

1. Using the dropper vial, add five drops (150  $\mu$ L) of Sample Diluent Buffer to a small test tube.
2. Mix broth culture thoroughly by gently swirling the tube. Using the transfer pipette supplied with the kit, add 150  $\mu$ L of Broth Culture Growth (second mark from tip of pipette) to the tube containing Sample Diluent.
3. Gently mix the contents of the tube with the transfer pipette by squeezing the pipette bulb 3 times. Alternatively, you can mix using a vortex for 10 seconds. Return the transfer pipette to the tube for later use.
4. Bring all Test Devices, reagents and samples to room temperature (20-25°C) before testing. Remove the Test Device from its foil pouch. Label the device with the patient's identification.
5. Using the transfer pipette provided in the kit, add 150  $\mu$ L of the diluted specimen (second mark from tip of pipette) to the sample port of the device. Incubate the test at 20-25°C for 20 minutes. Read results within 1minute.

## Interpretation of Results

Visual

Negative Test:

PINK-RED band at the Control line position. No other bands are present.

Positive Test for Shiga toxin 1:

PINK-RED bands at Control and Toxin 1 line positions. No bands at the Toxin 2 test line.

Positive Test for Shiga toxin 2:

PINK-RED bands at Control and Toxin 2 line positions. No bands at the Toxin 1 test line.

Positive Test for Shiga toxins 1 and 2:

PINK-RED bands at the Control, Toxin 2, and Toxin 1 line positions.

Invalid Test Results:

1. No band at the designated position for the Control line.
2. PINK-RED band appearing at either the Toxin 1 or Toxin 2 Test line position of the device after the defined incubation limit or a band of any color other than PINK-RED.

## Sensitivity

Mac broth: 93.8%

GN broth: 89.1%

SMAC plate: 100%

## Specificity

Mac broth: 99.7%

GN broth: 99.7%

SMAC plate: 99.6%