



ImmunoCard STAT! EHEC

Lateral flow test for the detection of *E. coli* Shiga Toxins 1 & 2 from enriched stool specimens



Rapid Shiga Toxins 1 and 2 detection, the new standard for EHEC infection diagnosis

Enterohemorrhagic *E. coli* (EHEC) infection may progress from mild diarrhoea to HUS (Hemolytic Uremic Syndrome), a life-threatening illness resulting in significant renal failure particularly in children and elderly.

Empiric treatment of the infection with antibiotics has been associated with higher risk of developing HUS¹.

Sorbitol McConkey culture detects *E. coli* O157 with 50-60% sensitivity² but this serotype only represents 15-20% of all EHEC isolates in most European countries.

The CDC recommends to screen for Shiga Toxins all stool samples submitted for Enteric Pathogens testing³.

- Detection of all Shiga Toxin-producing *E. coli* – not O157:H7 only
- Rapid 20 minutes lateral flow test from overnight enriched stool specimens
- Differentiation between Shiga Toxin 1 and Shiga Toxin 2
- High performance: 92.1% Sensitivity - 100% Specificity

¹Thorpe, "Shiga Toxin-Producing *Escherichia coli* Infection", *Clinical Infectious Disease*, 2004, 38:1298-303.

²Kehl, "Role of the Laboratory in the Diagnosis of Enterohemorrhagic *Escherichia coli* Infections", *Journal of Clinical Microbiology*, 2002, 40:2711-2715.

³Centers for Disease Control-USA "Recommendations for Laboratory Identification of Shiga toxin-producing *E. coli* (STEC)", *MMWR*, September 29, 2006, 55:1045.

Test Procedure



BROTH ENRICHMENT

1. Gently mix unpreserved specimen.
2. Using a pipettor or transfer pipette (not supplied with the kit), add 50 µL* 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.

TEST PROCEDURE

1. Using the dropper vial, add five drops (150 µL) 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 µL 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 ImmunoCard STAT!® EHEC 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 µL 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 1 minute.

RESULTS

<p>POSITIVE</p>	<p>NEGATIVE</p>	<p>INVALID</p>
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*This chart does not contain complete instructions for use. For further information, please refer to the package insert.

Ordering Information	Product	Test Size	Catalog no.
	ImmunoCard STAT!® EHEC	30 test cards	751630
Other Meridian Products	Premier™ EHEC	96 Microwells	608096
	ImmunoCard STAT!® E. coli 0157 Plus	30 Test Cards	750530

DISTRIBUTED BY



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