## I. Intended Use

The Biomerica *Shigella* species test is a lateral flow immunoassay for the rapid determination of the presence of *Shigella* species in human stool samples. The test is intended for professional use only.

## II. Summary and Explanation

Shigellosis is an acute inflammatory gastroenteritis that spreads through contaminated food and water that is passed on from person to person. The causative agents of Shigellosis are the members of the *Shigella* genus, i.e. *Shigella dysenteriae, Shigella flexneri, Shigella boydii, and Shigella sonnei*. The symptoms of *Shigella* infection are multiple bouts of loose stools that may contain blood or pus, and fever and stomach cramps that last usually from 5 to 7 days. *Shigella flexneri* also causes a long-term disorder known as post-infectious arthritis. The symptoms of the disorder range from joint pains, irritation of the eyes and painful urination.[1] *Shigella* species infection can also induce encephalopathy in adults that may happen simultaneously or precede the gastrointestinal signs.[2]

Identification of *Shigella* species is done by bacterial culture[3], a time consuming procedure that can last up to a few days. For the appropriate treatment to be given, and more importantly, for timely anti-epidemic measures to be implemented more rapid tests are required. These tests include antibody-based Enzyme-Linked Immunosorbent Assay (ELISA)[4-5] and molecular testings[4,6] .These methods are quicker than culture methods and just as reliable. However, all these methods cannot be done in resource limited settings, at the patient's bedside or point-of-care (POC). Lateral flow diagnostic tests are reliable, quicker than culture, ELISA and molecular methods, and have the additional advantage of being POC and cost-effective, even for resource limited settings.[7]

## III. Principle of the Procedure

The *Shigella* species test utilizes the principle of non-competitive immunoassay. If *Shigella* species are present in the sample at concentrations above the detection level, a *Shigella* species specific antibody conjugated to colloidal gold binds to the antigen forming an antigen-antibody conjugate complex. An antibody which is immobilized in the Test region ("T") of the membrane is reactive to another epitope of the *Shigella* species. The capture antibody will then react with the antigen-antibody conjugate complex. The captured complex will appear as a pink color band on the membrane. A distinct green color band will always appear at the Control region ("C") indicating that the test is functioning properly.

## IV. Materials Provided

1. Test device in foil pouch
2. Stool collection vial with buffer
3. Instruction manual

## V. Materials Required but Not Provided

Timer and Gloves

## VI. Warnings and Precautions

**Safety Precautions:** Human stool should be handled as if capable of transmitting infectious agents. It is recommended that these specimens be handled using established good laboratory working practices. The test should be discarded in a proper biohazard container after testing.

**For *in vitro* diagnostic use:** Do not use the kit beyond the expiration date printed on the outside of the foil pouch. Discard all used test devices into a proper biohazard container. The test should remain in the sealed pouch until use. Do not use the test if pouch is damaged. The test must be carried out within 2 hours of opening the sealed pouch.

## VII. Kit Storage

The *Shigella* species tests can be stored refrigerated or at room temperature (2-30°C). The test is usable until the expiration date stamped on the foil pouch.

## VIII. Quality Control

Although the *Shigella* species test contains an internal quality control (green color band in the Control region) good laboratory practice recommends the daily use of an outside control to ensure proper kit performance. Quality control samples should be tested according to the quality control requirements established by your laboratory.

## IX. Test Procedure

**Pre-treatment of the collected stool samples (see illustration 1):**

Unscrew the cap of the provided stool collection vial filled with buffer. Using the stick on the cap collect about a pea size (150 mg) of solid sample. Place the stick back into the vial and close it. For liquid sample, aspirate about 150 µL into the vial and close it. Shake the vial thoroughly until the sample is dispersed well in buffer. Use a separate specimen collection vial for each sample being tested.

**Test Procedure (see illustration 2):**

**Always allow the test devices, stool samples and stool collection vials to reach room temperature (15-30ºC) prior to testing. Do not open pouches until ready to perform the assay.**

1. Remove the *Shigella* species device from its sealed pouch and use it as soon as possible.
2. Shake the specimen collection vial to ensure good sample dispersion. Break off the tip of the vial.
3. Dispense exactly 4 drops or 100 µL into the specimen well (S). Start the timer. Use a separate device for each sample
4. Read the result at **10 minutes** after dispensing the sample.

**Illustration 1**

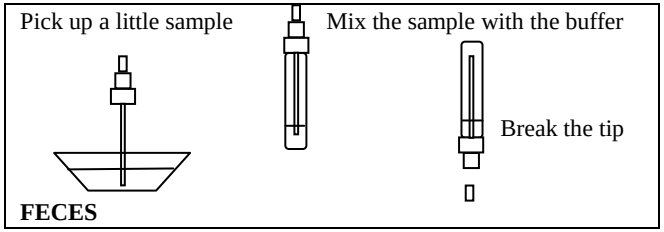
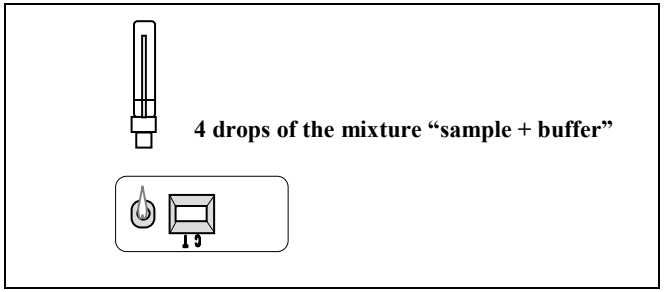
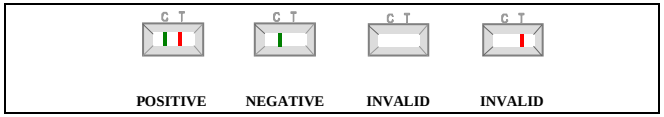



**Illustration 2**




## X. Interpretation of Results

**Illustration 3**




**POSITIVE:** Two lines appear across the central window, in the Test region (a pink test line in the region marked with the letter T) and in the Control region (a green control line in the region marked with the letter C).

**NEGATIVE:** Only one band appears in the Control region (a green control line in the region marked with the letter C).

**INVALID**: A total absence of the control line regardless of the appearance of the test line. Note: Insufficient specimen volume, incorrect procedural techniques or deterioration of the test materials are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit and contact your local supplier.

The intensity of the pink colored band in the test region (T) will vary depending on the concentration of antigens in the specimen. However, neither the quantitative value, nor the rate of increase in antigens can be determined by this qualitative test.

Internal procedural controls are included in the test:
- A green line appearing in the control region (C) confirms sufficient specimen volume and correct procedural technique.

## XI. Performance Characteristics

**Sensitivity and specificity**

Stool samples were studied using the Biomerica *Shigella* species test yielding 99% sensitivity and >99% specificity.

The use of a mouse monoclonal antibody in *Shigella* species ensures high degree of specificity for the detection of these bacteria. The antibodies used in this test recognize *Shigella* species epitopes found in stool of patients, as well as in preparations from bacteria cultures *in vitro.*

**Cross-reactivity**

A study was performed to determine the cross reactivity of the Biomerica *Shigella* test. No cross reactivity was found to common intestinal pathogens, other organisms and substances present in feces *(H. pylori, Escherichia coli O157:H7, Astrovirus, Rotavirus, Adenovirus, Campylobacter, Salmonella).*

## XII. Limitations of the Test

1. The test is a qualitative method for stool samples only. It is not meant for quantitative analysis.
2. Excessive amount of the sample applied to the specimen well can make the background appear dark which may lead to a difficult interpretation of the result. In such a case, the sample should be diluted and the test repeated.
3. If a negative result is obtained and clinical symptoms persist, additional testing using other clinical methods and/or seeing a physician is recommended. A negative result does not preclude the possibility of *Shigella* species infection.
4. Test results should be used as an aid in diagnosis and should not be interpreted as diagnostic by themselves.

## XIII. References


1. CDC *Shigella* Homepage
http://www.cdc.gov/nczved/divisions/dfbmd/diseases/shigellosis
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## XIV. Ordering information

Ordering Information:


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IVD

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CE

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For Export Only

# EZ-SHIGELLA

## One-Step *Shigella* species Rapid Test

**January 2012**

REF **1009**

Immunoassay for the qualitative determination of *Shigella* species in human stool specimen

FOR *IN VITRO* DIAGNOSTIC USE ONLY

**FOR PROFESSIONAL USE ONLY**

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