MONLAB

MonlabTest®

Shigella MonlabTest®

CE

IVD

MO-804026 20 TESTS

One step test to detect Shigella

A rapid, one step test for the qualitative detection of *Shigella* in human feces.
For professional in vitro diagnostic use only.

MATERIALS PROVIDED	MATERIALS REQUIRED BUT NO PROVIDED
- 20 Tests - Instruction for use - 20 Specimen collection vial with buffer - 1 Control -: negative swab + testing tube + pipette - 1 Control +: positive swab + testing tube + pipette	- Specimen collection container - Disposable gloves - Timer

INTENDED USE

Shigella MonlabTest® is a rapid chromatographic immunoassay for the qualitative detection of *Shigella* in stool samples in order to detect shigellosis in infected human.

SYNTHESIS

Clinical syndromes in humans caused by infection with *Shigella* are divided into *S. dysenteriae, S. flexneri, S. boydii* y *S. sonnei*, and a range of clinical syndromes, including diarrhoeal disease, fever and stomach cramps. Shigellosis are associated with poor sanitation, contaminated food and water, and crowded living conditions and usually resolves in 5 to 7 days. The predominant serogroups of *Shigella* are particularly common and It causes recurrent problems in settings where hygiene is poor and can sometimes sweep through entire communities.
Shigella MonlabTest® provides a rapid detection of *Shigella* directly from the fecal samples.

PRINCIPLE

The *Shigella* MonlabTest® is a qualitative lateral flow immunoassay for the detection of *Shigella* in human feces samples. The membrane is pre-coated with antibodies against *Shigella* antigens on the test line region. During testing, the sample reacts with the particle coated with anti-*Shigella* antibodies which was pre-dried on the test strip. The mixture moves upward on the membrane by capillary action. In the case of a positive result the specific antibodies present on the membrane will react with the mixture conjugates and generate coloured lines. A green coloured band always appears in the control line and serves as verification that sufficient volume was added, that proper flow was obtained and as an internal control for the reagents.

PRECAUTIONS

- For professional *in vitro* diagnostic use only.
- Do not use after expiration date.
- The test should remain in the sealed pack until use.
- Do not use the test if pack is damaged.
- Follow Good Laboratory Practices, wear protective clothing, use disposal gloves, do not eat, drink or smoke in the area.
- All the specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The test should be discarded in a proper biohazard container after testing.
- The test must be carried out within 2 hours of opening the sealed bag.

STORAGE AND STABILITY

Store as packaged in the sealed pack either at refrigerated or room temperature (2-30ºC/36-86ºF). The test is stable through the expiration date printed on the sealed pack. The test must remain in the sealed pack until use. Do not freeze.

SPECIMEN COLLECTION AND PREPARATION

Collect sufficient quantity of feces (1-2 g or mL for liquid sample). Stool samples should be collected in clean and dry containers (no preservatives or transport media). The samples can be stored in the refrigerator (2º-8ºC/36º-46.4ºF) for 1-2 days prior to testing. For longer storage (maximum 1 year) the specimen must be kept frozen at -20ºC/4ºF. Freezing and thawing cycles are not recommended. In this case, the sample will be totally thawed, and brought to room temperature before testing.

PROCEDIMIENTO

To process the collected stool samples (see illustration 1):
Use a separate specimen collection vial for each sample (with 1mL of the buffer). Introduce the swab or stick two or three times into the fecal specimen to pick up the sample (approx. 125 mg) and put into the testing tube or vial with buffer. Shake the testing tube or vial in order to assure good sample dispersion. For liquid stool samples, aspirate the fecal specimen with a dropper and add 125µL into the testing tube or vial with buffer.
Test Procedure (see illustration 2)
Allow the tests, stool samples and buffer to reach to room temperature (15-30°C/59-86°F) prior to testing. Do not open pouches until ready to perform the assay.
1. Remove the *Shigella* MonlabTest® from its sealed pouch and use it as soon as possible.
2. Shake the specimen collection vial to assure good sample dispersion. Break off the top of the vial.
3. Use a separate device for each sample. Dispense 4 drops into the specimen well (S). Start the timer.
4. Read the result at **10 minutes** after dispensing the sample.

Illustration 1

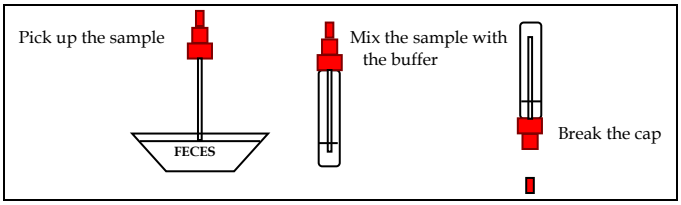
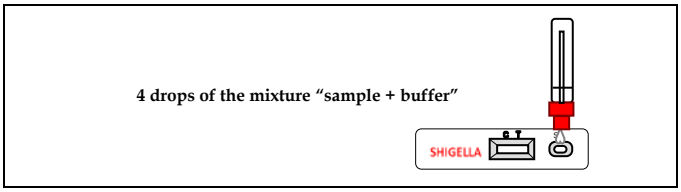


Illustration 2



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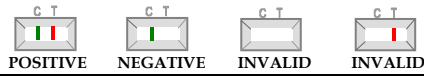
INTERPRETATION OF RESULTS

Illustration 3



POSITIVE**:** Two lines appear across the central window. In the result line region, a **red** test line marked in the illustration 3 with the letter T, and in the control line region, a **green** control line marked in the illustration 3 with the letter C.

NEGATIVE**:** Only one **green** band appears across the control line region marked with the letter C at the illustration 3 (control line).

INVALID: Total absence of the **green** control coloured band regardless the appearance or not of the **red** test line. See illustration Note: Insufficient specimen volume, incorrect procedural techniques or deterioration of the reagents 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 distributor.

NOTES ON THE INTERPRETATION OF RESULTS

The intensity of the red coloured band in the result line 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.

QUALITY CONTROL

Internal procedural controls are included in the test:

- A green line appearing in the control line region (C). It confirms sufficient specimen volume and correct procedural technique.

External Quality Control

Each kit contains a positive and negative control material. Use the control swabs to check that the extraction reagents and the test are working properly. Also use the controls to test that you are able to correctly perform the test procedure.

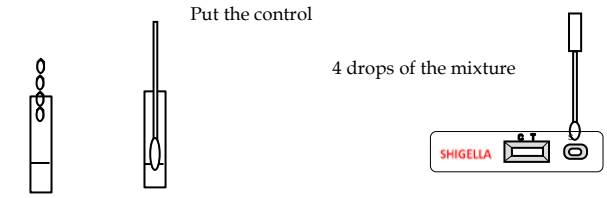
Quality Control Procedure:

Shigella Positive control: Remove the *Shigella* positive control from its sealed pouch. Add the diluent (15 drops) in a testing tube. Put the *Shigella* positive control swab, mix 60 seconds and extract as much liquid possible from the swab. Discard the swab. Remove the test from its sealed pouch and dispense 4 drops of the positive control liquid into the specimen well (S).

Result: *Shigella* positive (see interpretation of results).

Shigella Negative control: Repeat the procedure for Negative Swab Control using the Reagent Control (-) instead the Reagent Control (+)

Result: *Shigella* negative (see interpretation of results).



LIMITATIONS

1. *Shigella* MonlabTest® will only indicate the presence of *Shigella* in the specimen (qualitative detection) and should be used for the detection of *Shigella* antigens in feces specimens only. Neither the quantitative value nor the rate of increase in antigen concentration can be determined by this test.
2. An excess of sample could cause wrong results (brown bands appear). Dilute the sample with the buffer and repeat the test.
3. Some stool samples can decrease the intensity of the control line.
4. Si If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of *Shigella* infection.
5. After one week of infection, the number of virus in feces is decreasing, making the sample less reactive. Stool samples should be collected within one week of the onset of symptoms.
6. This test provides a presumptive diagnosis of *Shigellosis*. All results must be interpreted together with other clinical information and laboratory findings available to the physician.

EXPECTED VALUES

Every year, about 14,000 cases of shigellosis are reported in the United States. Because many milder cases are not diagnosed or reported, the actual number of infections may be twenty times greater. Shigellosis is particularly common and causes recurrent problems in settings where hygiene is poor and can sometimes sweep through entire communities. It is more common in summer than winter.

PERFORMANCE CHARACTERISTICS

Sensitivity and specificity

It was performed an evaluation using *Shigella* MonlabTest®. It was studied some stool samples and the results confirmed by culture. *Shigella* MonlabTest® showed >99% of sensitivity and >99% of specificity.

Cross-Reactivity

It was performed an evaluation to determine the cross reactivity of *Shigella* MonlabTest®. There is not cross reactivity with common gastrointestinal pathogens.

- *Escherichia coli O157:H7*
- *Helicobacter pylori*
- *Listeria monocytogenes*
- *Salmonella*
- *Staphylococcus aureus*
- *Yersinia enterocolitica*

REFERENCES

- B Matyas. MD, et al, "Preliminary FoodNet Data on the Incidence of Infection with Pathogens Transmitted Commonly Through Food —10 States, 2009". MMWR; April 2010, Vol.16. No 14, p.418-422.
- Shah M. Faruque. Et al, "*Shigella dysenteriae* Type 1-Specific Bacteriophage from Environmental Waters in Bangladesh". Applied and Environmental Microbiology, Dec 2003. Vol.69. No 12, p 7028-7031.

SYMBOLS FOR IVD COMPONENTS AND REAGENTS

	Manufacturer	IVD	For i*n vitro* diagnostic use only
	Don't re-use		Consult instructions for use
Σ n	Contains sufficient for <n> tests		Keep dry
REF	Catalogue Code		Temperature limitation
LOT	Lot Number		Use by

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