QUALITY CONTROL

PREPARATION NOTES:
1. Bring all control reagents to 20-26 C before testing.
2. Use 1 Test Device for each control reagent.
3. A blue line at the Control Line serves as a positive internal control.
4. A clear background around Test and Control Lines serves as a negative internal control.
5. The Positive Control and Sample Diluent reagents serve as external control reagents.
6. See the instructions for use supplied with this reagent for further discussion on the purpose of controls.

INTERPRETATION OF CONTROL RESULTS
1. Positive and Negative Controls must produce the expected results for positive and negative samples.
2. Do not report test results when control tests do not meet this specification.

TEST PROCEDURE

PREPARATION NOTES:
1. The specimen should be transported in an airtight container and stored at 2-8 C until tested.
2. Test specimen immediately, OR store at 2-8 C for up to 24 hours before testing. OR store frozen at -1-30 C before testing. Specimens may be frozen and thawed twice.
3. Bring all samples, Test Devices, and reagents to 20-26 C before testing.
4. Mix stool samples thoroughly regardless of consistency before testing.
5. Use 1 clean calibrated transfer pipette supplied with the kit for each sample.
6. Use 1 Test Device for each sample.
7. Use 1 Sample Diluent vial (red capped vial) for each sample.
8. The spot below represents a 5-6 mm circle.

NOTE: Stool in transport media, on swabs, or mixed with preservatives is not appropriate for testing.

TEST PREPARATION

1. Hold reagent vials upside down to disperse reagents.
2. Dispense 4 drops Positive Control to the test window (at arrow) of each Test Device. Do not touch the tip of vials to the Test Device.
3. Break the red tip from the red cap of an unused vial of Sample Diluent.
4. Dispense 4 drops of Sample Diluent to the test window (at arrow) of each Test Device. (Negative Control)
5. Set a timer and incubate the tests at 20-26 C for 5 minutes.
6. After 5 minutes, read results within 1 minute of test completion.

INTERPRETATION OF RESULTS

POSITIVE TEST:
Blue band at Control Line plus pink-red band at Test Line.
No other bands should be seen.
The background should not interfere with reading the test.

NEGATIVE TEST:
Blue band at Control Line only.
No other bands should be seen.
The background should not interfere with reading the test.

INVALID RESULTS:
1. Band at Test Line without band at Control Line, or
2. Band of wrong color at Test Line, or
3. No Test Line AND no Control Line, or
4. Test Line band that appears after 6 minutes.
Repeat invalid tests. DO NOT report results when test results are difficult to interpret or test results are invalid.