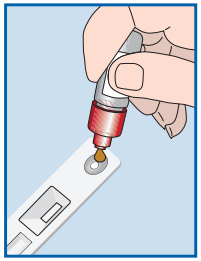
QUALITY CONTROL

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.



1. Hold reagent vials upside down to dispense reagents.
2. Dispense 4 drops Positive Control to the sample port (at arrow) of one Test Device. Do not touch the tip of vial 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 sample port (at arrow) of another 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 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.

Contact Meridian's Technical Support department at 513-271-3700 for technical assistance with this product.

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IMMUNOCARD STAT!® HPSA® TEST PROCEDURE

A Rapid Immunoassay for the Detection of Helicobacter pylori Antigen in Stool

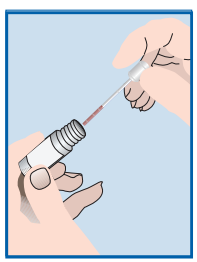
1 TEST PREPARATION

PREPARATION NOTES:

For Sample Diluent Vial

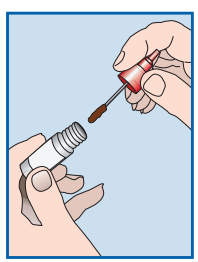
1. The specimen should be transported in an airtight container and stored at 2-8 C until tested.
2. Test specimens immediately, OR store at 2-8 C for up to 72 hours before testing, OR store frozen at ≤-20 C before testing. Specimens may be frozen and thawed twice.
3. Bring all samples, Test Devices and 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.



Liquid or semi-solid stool:

1. Unscrew the red cap from Sample Diluent (red capped) vial.
2. Use a clean calibrated transfer pipette (supplied with the kit) to draw mixed sample to the second mark from the pipette tip (100 uL).
3. Dispense the mixed sample into the Sample Diluent vial.
4. Use the transfer pipette to mix the diluted sample thoroughly but gently by squeezing the pipette bulb three times.
5. Recap the vial tightly and mix thoroughly but gently by swirling the contents of the vial for 15 seconds. Alternatively, mix for 15 seconds using a vortex mixer.



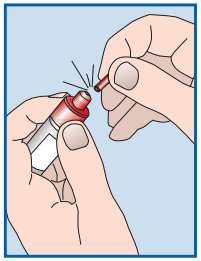
Solid or formed stool:

1. Unscrew the red cap from Sample Diluent (red capped) vial.
2. Use the white plastic applicator stick in the red cap to collect a small portion of stool (5-6 mm pellet). (See diagram under PREPARATION NOTES.)
3. Transfer the pellet to the Sample Diluent vial.
4. Recap the vial tightly and mix thoroughly but gently by swirling the contents of the vial for 15 seconds. Alternatively, mix for 15 seconds using a vortex mixer.

2 TEST PROCEDURE

PREPARATION NOTES:

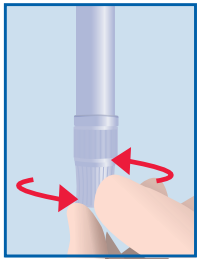
1. Remove the Test Device from its pouch and discard the pouch.
2. Label the device with the patient's name or control name.
3. The round window marked with an arrow is the test window where sample is added.
4. The Test Device is marked to indicate where test and control lines will appear.



If using Sample Diluent Vial:

1. Hold the diluted specimen vial upright and gently tap the bottom of the vial on the countertop before proceeding.
2. Cover the top of the diluted sample vial with absorbent paper to avoid splatter.
3. Break off the red tip on the outside of the red cap. (Do not break off the white applicator stick.)

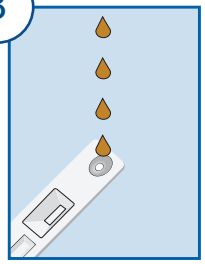
– OR –



If using Simple Sample™:

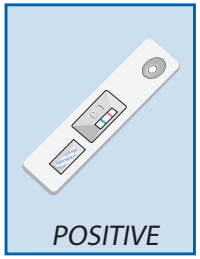
1. Mix sample by inverting tube several times.
2. Remove the cap from the tip of Simple Sample tube.

3



4. Hold the Sample Diluent vial or Simple Sample upside down and dispense 4 drops of diluted sample to the sample port (at arrow) of the Test Device. Do not touch the tip of vial to the Test Device.
5. Set a timer and incubate the test at 20-26 C for 5 minutes.
6. At the end of 5 minutes, read the results within 1 minute.

4 INTERPRETATION OF RESULTS

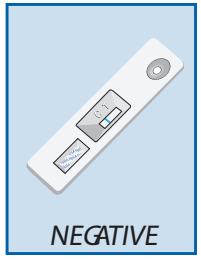


POSITIVE TEST:

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.

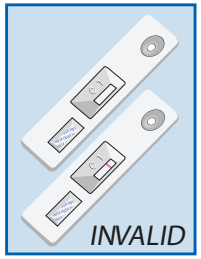


NEGATIVE TEST:

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.

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