

# **Triage Micro Parasite Panel**

## **Panel For Detection of *Entamoeba Hystolytica/Dispar*, *Giardia Lamblia*, and *Cryptosporidium Parvum***

\*\*\*See package insert for more information\*\*\*

### **Sample Collection:**

Only fresh or freshly frozen, un-fixed stool specimens have been evaluated using this kit. Stool specimens should be received in an airtight container and stored at 2-8°C until tested. Specimens should be tested as soon as possible.

### **Sample Preparation:**

1. Mix Specimen Diluent in bottle by inversion. Add the Specimen Diluent to the Fill Line on the Specimen Tube.
2. **Specimen addition**  
*Liquid Specimens:*  
Using the Transfer Pipet provided, transfer 500µL of specimen to the Specimen Tube.  
*Solid or Semi-solid Specimens:*  
Using the Sample Spoon provided, transfer a level spoonful of specimen to the Specimen Tube.
3. Recap the Specimen Tube with the blue cap and vortex for 10 seconds.
4. Following dilution and mixing of the sample, uncap the Specimen Tube and discard the blue Screw Cap. Slowly insert the Filter Device (white end first) into the Specimen Tube using one of the uncolored Screw Caps.
5. Place the Specimen Tube containing the Filter Device into a centrifuge and subject the sample to centrifugation for 5 minutes at 1500-1800 x g. After centrifugation, remove and uncap the Specimen Tube. **DO NOT REMOVE THE FILTER DEVICE FROM THE SPECIMEN TUBE.** The assay ready specimen will be accessible in the Filter Device through the uncapped Specimen Tube.

**Start the test procedure within ten minutes following the collection of filtrate.**

### **Test Procedure:**

1. **Add Sample**  
Using a transfer pipet, add 500µL of the filtered sample onto the center of the Detection Zone of the Test Device (use the 0.5mL mark on the pipet). When transferring specimen from the filter device to the Triage Device, take care not to touch the sides of the specimen tube with the transfer pipet. Allow the filtered sample to soak into the Test Device completely.
2. **Add Conjugate:**  
Using the Biosite Pipet and pipet tip provided, add 140µL of Enzyme Conjugate directly to the center of the Detection Zone of the Test Device and incubate for 3 minutes.
3. **Wash Twice:**  
Add 6 drops of Wash Solution onto the center of Detection Zone and allow the Wash Solution to completely soak into the Test Device. Add 6 additional drops of Wash Solution and allow to completely soak into the Test Device.
4. **Add Substrate:**

Add 4 drops of Substrate onto the center of Detection Zone and allow the Test Device to incubate for 5 minutes.

**5. Read Results:**

Immediately after the incubation, read the results at the Test Zones, the three POS CTRL, and the one NEG CTRL Zones.

**Interpretation of Results:**

If the background color of the Detection Zone obscures the visual appearance of any of the discrete zones, another sample consisting of ¼ of the initial sample should be processed using the same procedure as before and tested using a new Test Device.

**Read the Negative Control Zone:**

Results are valid if no color bar appears in the NEG CTRL Zone. If a color bar appears in the NEG CTRL Zone, discard the Test Device, prepare another sample consisting of ¼ of the initial sample volume, and test using a new Test Device.

If the same results are observed upon analysis of the new sample, contact Biosite Technical Services.

**Read All Three of the Positive Control Zones:**

Results are valid if a color bar appears in all three of the POS CTRL Zones. If a color bar does not appear in any or all of POS CTRL Zones, discard the Test Device and retest the sample using a new Test Device.

If the same results are observed upon analysis of the new sample, contact Biosite Technical Services.

**Read the G. Lamblia, E. Histo, and C. Parvum Test Zones:**

A colored bar appears adjacent to the name of the parasite in the Test Zone if the antigen specific for the parasite is present at concentrations equal to the analytical sensitivity of the test or greater. For example:

- A sample is positive for the *G. lamblia* antigen if a clearly distinct color bar appears in the Test Zone for *G. lamblia*, regardless of the intensity.
- If a clearly distinct color bar is not present in the Test Zone for *G. lamblia*, then the sample is negative for *G. lamblia*.
- A sample is positive for the *E. histolytica/dispar* antigen if a clearly distinct color bar appears in the Test Zone for *E. histolytica/dispar*, regardless of the intensity.
- A sample is negative for *E. histolytica/dispar* if no color bar is present in the *e. histolytica/dispar* Test Zone.
- A sample is positive for the *Cryptosporidium parvum* antigen if a clearly distinct color bar appears in the Test Zone for *Cryptosporidium parvum*, regardless of the intensity.
- A sample is negative for *Cryptosporidium parvum* if a color bar is not present in the *Cryptosporidium parvum* Test Zone.

- A sample is positive for two or more parasites if multiple lines are observed in the Test Zone adjacent to the names of the parasites.

**Quality Control:**

External Positive and Negative Control specimens should be prepared and tested in the same manner as liquid specimens.

An external positive control containing these same antigens at concentrations above the specified sensitivity for all three parasites should produce a color bar on the membrane adjacent to the names of the parasites on the Test Device.

Negative Controls should produce a color bar adjacent to the names of any of the parasites in the Test Zone.