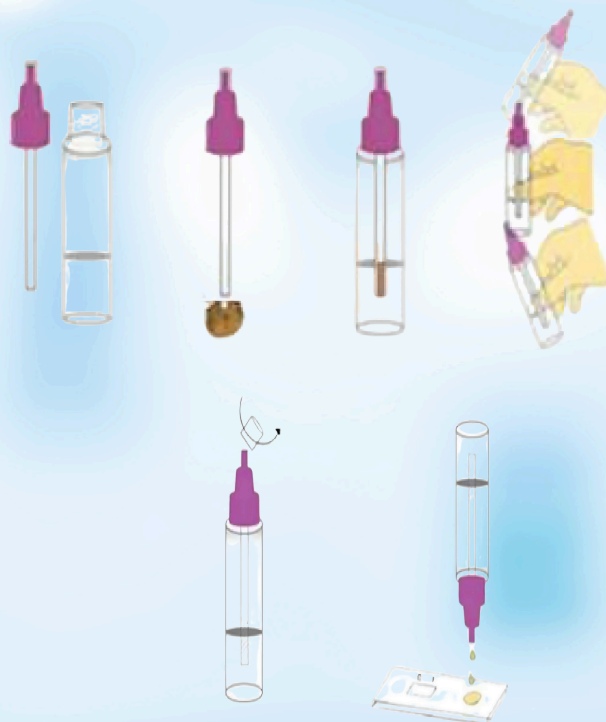


### INTERPRETATION OF RESULTS



### DIRECTIONS FOR USE

Allow the test device, specimen and/or buffer to equilibrate at room temperature (15-30°C) before testing.

1. Allow test device, Assay Buffer and specimen equilibrates to room temperature (15-30°C) prior to testing.

2. Remove the test device from the aluminum foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.

3. Unscrew the cap of the specimen collection tube with extraction buffer, then randomly stab the specimen collection applicator into the fecal specimen in at least 3 different sites. Take the dab of stool sample using applicator and add in to the 1 ml buffer in sample extraction tube. Mix well then kept for 10 minute. Add 2 drops (80 to 100µL) into the sample well.

4. Allow reaction to occur and read the results at 20 minutes. Do not interpret results after 30 minutes.



**Negative:** The control line is the only visible line on the test device.

**Positive:** The control line and Test line is visible line on the test device.

**Invalid:** The control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the likeliest reasons for control line failure. Repeat the test using a new test device.

## H.PYLORI Ag Rapid Test



## Sensitivity and Specificity

### Diagnostic Performance

Commercial H. Pylori Ag Rapid Test Results	H. Pylori Ag Rapid Test		Total
	Positive	Negative	
Positive	35	0	35
Negative	0	50	50
Total	35	50	85

Relative Sensitivity: 100%, Relative Specificity: 100.0%,  
Overall Agreement: 100.0 %.

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