

# QwikID™ H. pylori

## RAPID ANTIGEN TEST



### INTENDED USE

**QwikID™ H. pylori Rapid Antigen Test** is an FDA cleared *in vitro* diagnostic lateral flow assay for the qualitative detection of *H. pylori* antigen in human stool specimens.

### FEATURES

**Method:** Monoclonal immunochromatographic assay

**Specimen:** Stool

**Detection Device:** Lateral flow cassette

**Time to Result:** 10 minutes

**Internal Quality Control:** Positive control reagent

**Package:** 20 tests/kit

**Storage Temperature:** 15-30°C



Cat. no. **IG06020C03**

### PERFORMANCE CHARACTERISTICS

**Percent Positive Agreement:** 96.7%

**Percent Negative Agreement:** 98.2%

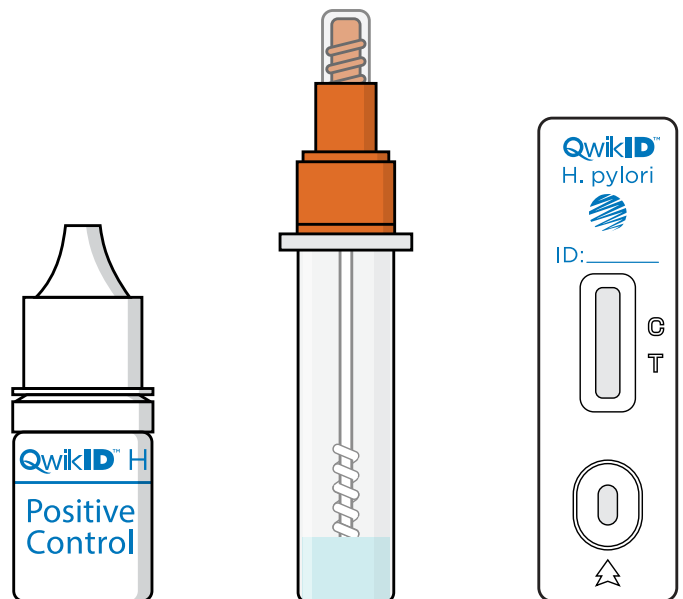
**Overall Percent Agreement:** 97.9%

### ANALYTICAL SENSITIVITY

The analytical sensitivity was evaluated using five *H. pylori* strains.

The LoD was determined to be  $8.5 \times 10^5$  CFU/mL for *H. pylori* strain ATCC 43504

### MATERIALS



(x1)  
Positive  
Control  
Reagent

(x20)  
Sample Preparation  
Tube with "Sampler"  
Attached to Tube Cap

(x20)  
Test  
Cassette

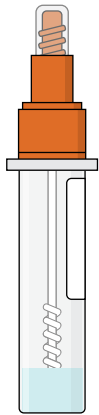
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## RAPID ANTIGEN TEST

### Test Procedures and Results\*

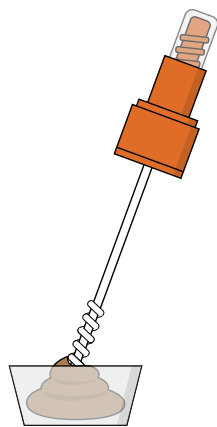
#### Step 1

Take out sample preparation tube. Label the tube accordingly.



#### Step 2

Unscrew orange sample preparation tube cap. Place the "sampler" into the stool specimen to obtain 30-50mg stool (a rice-like size.) An excess of stool sample could cause invalid results.



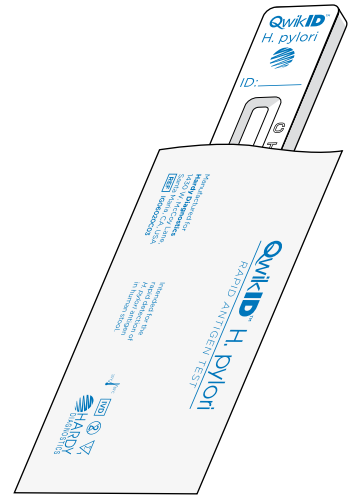
#### Step 3

Put the "sampler" back into sample preparation tube and tighten securely. Mix thoroughly by inversion, shaking or vortex the tube for at least one minute.



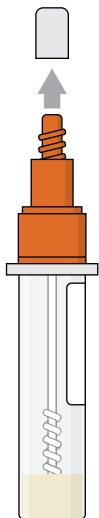
#### Step 4

Remove a test cassette from its foil pouch and place it on a flat surface. Label the cassette with the sample information.



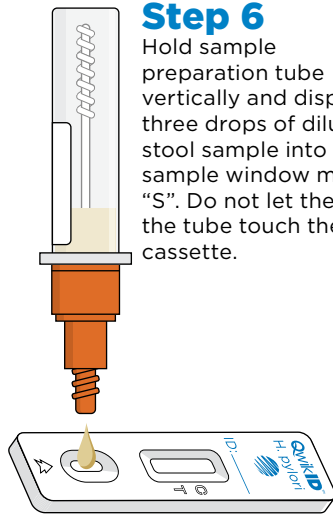
#### Step 5

Take the clear cap off of the orange sample preparation tube tip.



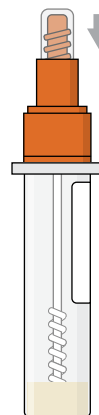
#### Step 6

Hold sample preparation tube vertically and dispense three drops of diluted stool sample into the sample window marked "S". Do not let the tip of the tube touch the test cassette.



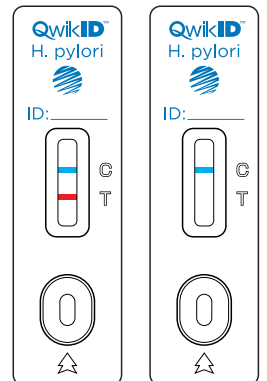
#### Step 7

Put the clear cap back onto the tube. Properly dispose the sample tube.



#### Step 8

Read results at ten (10) minutes.



Positive

Negative

**HARDY**  
DIAGNOSTICS  
*A Culture of Service™*

\* Refer to Instructions for Use for complete instructions.