

# Status

# H. pylori

Rapid immunoassay for the qualitative detection of anti-Helicobacter pylori antibodies in human whole blood, serum or plasma



- **CLIA Waived** for whole blood
- Sensitivity of 95.9% with 91.6% overall agreement to biopsy histology
- Easy-to-use single reagent procedure
- Results available in 10 minutes
- Requires only 25µl of whole blood or 10µl serum/plasma
- Convenient finger stick sample collection

## CPT CODE

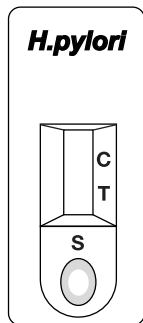
**86318QW**

**Whole Blood**

**86318**

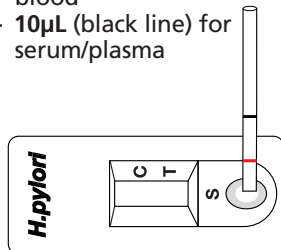
**Serum/Plasma**

**STEP 1**  
Remove a test device from its pouch and place on a flat surface.

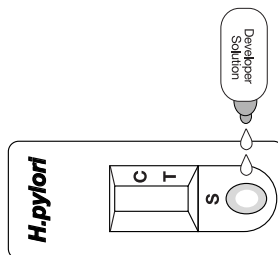


**STEP 2**  
Collect sample using the capillary tube provided and add to test device Sample Well.

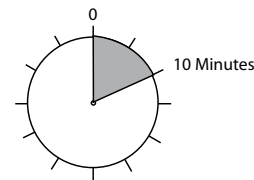
- 25µL (red line) for whole blood
- 10µL (black line) for serum/plasma



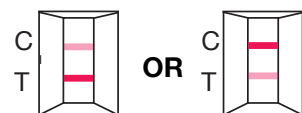
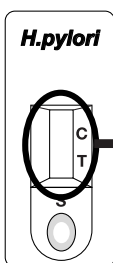
**STEP 3**  
Add 2-3 drops of Developer Solution into Sample Well.



**STEP 4**  
Read the results at 10 minutes.

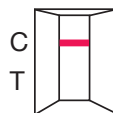


## INTERPRETATION OF RESULTS



Two Lines  
Positive (+)

**Any visible T line  
is positive**



C Line only  
Negative (-)



No C Line  
Invalid

**Repeat with new  
sample and device**

## ORDERING INFORMATION

PRODUCT	# OF TESTS	ITEM #
Status H. Pylori(whole blood,serum or plasma)	30	37030
CONTROL PRODUCT	# OF TESTS	ITEM #
Status H. Pylori Control Set	2 x 2 ml	200013



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iFOBT • Flu A&B • Fertility • Bladder Cancer Marker

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