



WHO urges *H. pylori* Screening to Prevent Gastric Cancer

CTK Offers CE marked *H. pylori* Ab screening test and Ag active infection detection test to aid in gastric ulcer management

H. pylori is known to be a major cause of gastric ulcers: 90% of duodenal and 80% of gastric ulcers, which double a person's risk of gastric cancer.

H. pylori infection can be diagnosed via:

- Non specific breath test
- Invasive biopsy urease test
- Invasive biopsy culture test
- *H. pylori* antibody ELISA or Rapid Test
- *H. pylori* fecal antigen test

CTK offers two simple accurate cost effective methods to aid in management of *H. pylori* infection:

- The *OnSite* *H. pylori* antibody rapid test (Catalog No.R0191C) detects antibodies in blood specimens for initial screening of *H. pylori* infection history.
- The *OnSite* *H. pylori* Ag Rapid Test (Catalog No. R0192C) detects *H. pylori* antigen shed in feces as an indication of active infection or effectiveness of treatment.

The ***OnSite*** *H. pylori* Rapid Tests utilize reagents developed in-house at CTK's ISO:13485, GMP certified facilities to ensure test quality, delivery time, and cost effectiveness.



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***OnSite* *H. pylori* Rapid Tests**

Cat. No.	Product	Detection	Sample	Test Time
R0191C	<i>H. pylori</i> Ab Combo Rapid Test CE	2 line test detects IgG, IgA, IgM to <i>H. pylori</i>	S,P & Whole blood	15 min
R0192C	<i>H. pylori</i> Ag Rapid Test CE	2 line test detects <i>H. pylori</i> specific antigen	Feces	15 min



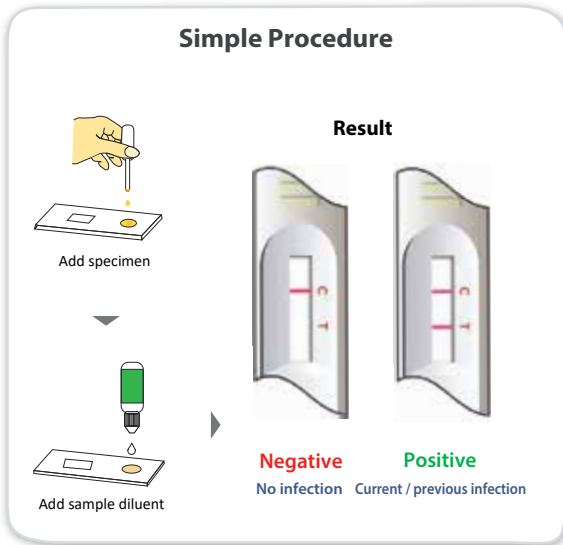
***OnSite* *H. pylori* Ab Combo Test**



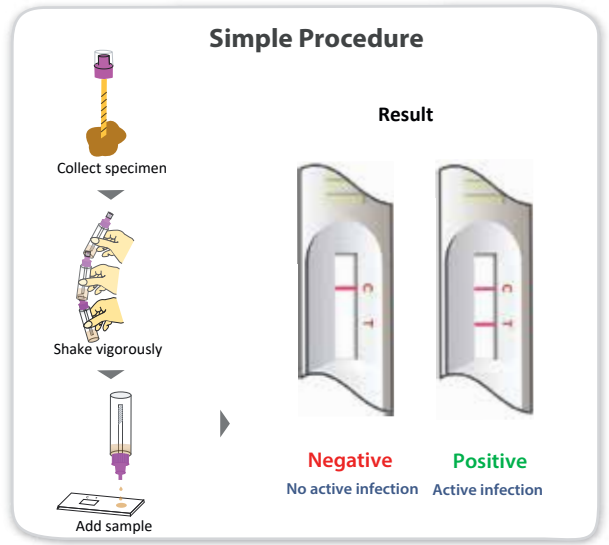
***OnSite* *H. pylori* Ag Rapid Test**

OnSite H. pylori Rapid Tests at a Glance

OnSite H. pylori Ab Combo Test (R0191C)



OnSite H. pylori Ag Rapid Test (R0192C)



Clinical Performance

A total of 200 specimens from non-*H. pylori* infected patients and 75 specimens from patients undergoing anti-*H. pylori* treatment were tested with the **OnSite H. pylori Ab Combo Rapid Test**.

Reference	OnSite H. pylori Ab Combo RDT		Total
	Positive	Negative	
Positive	65	10	75
Negative	18	182	200
Total	83	192	275

Relative Sensitivity: 86.7% , Relative Specificity: 91%
Overall Agreement: 89.8%

Clinical Performance

324 patient fecal samples were collected and tested on the **OnSite H. pylori Ag** and Urea Breath Test (UBT). Comparison for all subjects is shown in the following table:

UBT	OnSite H. pylori Ag RDT		Total
	Positive	Negative	
Positive	118	7	125
Negative	0	199	199
Total	118	206	324

Relative Sensitivity: 94.4% , Relative Specificity: 100%
Overall Agreement: 97.8%



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Comparison of H. pylori Tests on the Market

Test	Method	Sample	Preparation	Test Time
Antibody test	Lateral flow rapid test	Serum, plasma, whole blood	None	15 minutes
	ELISA test	Serum, plasma	None	90 minutes
Antigen test	Lateral flow rapid test	Feces	May avoid certain medications	15 minutes
Urea breath test	Scintillation counts for urease activity	Breath	One month long preparation Drink radioactive liquid	10 minutes
Rapid urease test	Tissue urease activity	Tissue biopsy	Fasting Avoiding certain medications	90 minutes
Culture	Culturing <i>H. Pylori</i>	Tissue biopsy	Fasting Avoiding certain medications	3 days



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