CTK BIOTECH
SIMPLIFYING DIAGNOSTICS

H. pylori Ab + Ag

Simple Accurate *H. pylori* Diagnostic Resource

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 # R0191C) detects antibodies in blood specimens for initial screening of *H. pylori* infection history.
- The *OnSite* H. pylori Ag Rapid Test (Catalog # 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.

OnSite H. pylori Rapid Tests

Catalog	Product	Detection	Sample	Test Time
R0191C	*H.pylori* Ab Combo Rapid Test CE	2 line test detects IgG, IgA, IgM to *H.pylori*	S,P & Whole blood	15 min
R0192C	*H.pylori* Ag Rapid Test CE	2 line test detects *H.pylori* specific antigen	Feces	15 min

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

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

CTK
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OnSite H. pylori Rapid Tests at a Glance

OnSite H. pylori Ab Combo Test (R0191C)

Procedure

Positive
Current infection or previous infection

Negative
No infection

Clinical Performance

324 patient serum samples were collected and tested on the *OnSite* H. pylori Ab Combo Test and a FDA approved *H.pylori* Ab rapid test. Comparison for all subjects is shown in the following table:

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

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

OnSite H. pylori Ag Rapid Test (R0192C)

Procedure

Positive
Active infection

Negative
No active infection

Clinical Performance

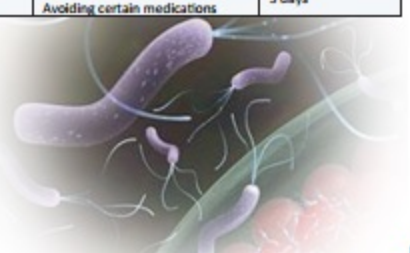
324 patient fecal samples were collected and tested on the *OnSite* H. pylori Ag and Urea Breath Test (UBT). Comparison for all subjects is shown in the following table:

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

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

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 *H. Pylori*	Tissue biopsy	Fasting Avoiding certain medications	3 days



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