



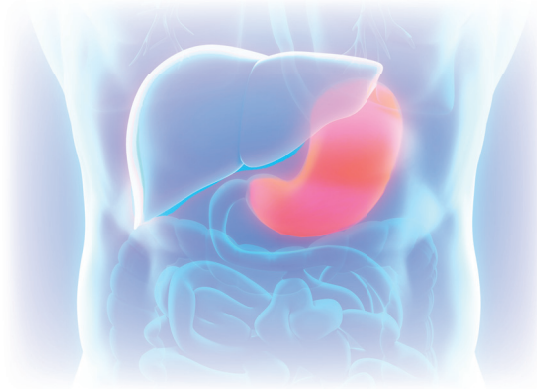
# Aria

## H. pylori Ab + Ag

Simple Accurate H. pylori Diagnostic Solution



CTK Offers CE marked *H. pylori* antibody screening test, as well as antigen test for the detection of active infection, 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:

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

CTK offers two simple accurate cost effective methods to aid in management of *H. pylori* infection, these tests utilize reagents developed in-house at CTK's ISO:13485, GMP certified facilities to ensure test quality, delivery time and cost effectiveness.

Catalog	Product	Detection	Sample	Test Time
R0191C	H.pylori Ab Combo Rapid Test <sup>CE</sup>	2 line test detects IgG, IgA, IgM to H. pylori	S/P/WB	15 min
R0192C	H.pylori Ag Rapid Test <sup>CE</sup>	2 line test detects <i>H. pylori</i> specific antigen	Feces	15 min

### 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	15minutes
	ELISA test	Serum, plasma	None	90 minutes
Antigen test	Lateral flow rapid test	Feces	May avoid certain medications	15minutes
Urea breath test	Scintillation counts for urease activity	Breath	One month long preparation Drink radioactive liquid	10minutes
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



Aria RAPID TEST





# Aria H. pylori Rapid Tests

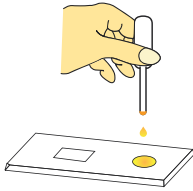
Simple Accurate H. pylori Diagnostic Solution

## Aria H. pylori Ab Combo Test (R0191C)

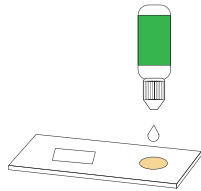
## Aria H. pylori Ag Rapid Test (R0192C)

### Simple Procedure

Add specimen



Add sample diluent



Negative (No infection)



Positive (Current / previous infection)



### Clinical Performance

#### Positive and negative specimens tested by *Aria* rapid test

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

#### Raw data of testing

Reference	<i>Aria</i> H. pylori Ab Combo Test		Total
	Positive	Negative	
Positive	65	10	75
Negative	18	182	200
Total	83	192	275

### Simple Procedure

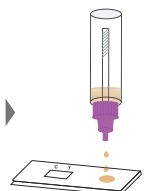
Collect specimen



Shake vigorously



Add sample



Negative (No active infection)



Positive (Active infection)



### Clinical Performance

#### Testing results by *Aria* rapid test vs. Urea Breath Test (UBT)

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

#### Raw data of testing

UBT	<i>Aria</i> H. pylori Ag Test		Total
	Positive	Negative	
Positive	118	7	125
Negative	0	199	199
Total	118	206	324

