

*Introducing . . .*

# ***H. pylori* Test Reagent for Chemistry Analyzers**

*Fully automated assay for the qualitative determination of *H. pylori* antibodies in human serum and plasma by immunoturbidimetric assay on automated clinical chemistry analyzers.*

## **Background:**

*Helicobacter pylori* is a gram-negative bacterium usually found in the stomach. *H. pylori* infection may be present in more than half the people in the world. In general, people infected with *H. pylori* are asymptomatic. However, individuals infected with *H. pylori* have a 10 to 20% lifetime risk of developing peptic ulcers and a 1 to 2% risk of acquiring stomach cancer. Anti-*H. pylori* antibody detection is useful in the diagnosis and treatment of *H. pylori* infection.

*H. pylori* testing methods such as histology, urease testing, culture, and PCR require that each patient undergo an invasive endoscopic biopsy. Urea breath tests require that the patient drink a <sup>13</sup>C or <sup>14</sup>C-labeled urea solution. Fecal antigen tests require that each patient collect and bring in stool samples. The **K-ASSAY® *H. pylori*** test requires no endoscopy, no solution to drink, no stool collection, and no need to separate samples for ELISA.

## **Features:**

- **Non-invasive and economical screening method for *H. pylori* infection**
- **Applicable to most automated chemistry analyzers**
- **Serum or plasma samples**
- **Excellent correlation to endoscopic biopsy + rapid urease testing and ELISAs**
- **No need to split samples between the chemistry analyzer and other methodologies such as ELISA**

*For research use only in the U.S. Not for use in diagnostic procedures in the U.S.*

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# K-ASSAY<sup>®</sup> *H. pylori* Test Reagent

## Product Overview

Assay Type	Immunoturbidimetric assay reagent for automated chemistry analyzers
Sample Type	Serum or Plasma
Sample Volume per Test	3.5 µL
Measurement Unit	U/mL
Measuring Range (undiluted samples)	3 - 100 U/mL
Negative / Positive Cutoff Point	10 U/mL
Prozone Effect	>900 U/mL
Agreement with <i>H. pylori</i> EIAs	>90%
Agreement with endoscopic biopsy tests	>90%

## Method Comparison

- Endoscopic Diagnosis of Atrophic Gastritis + Rapid Urease Test  
vs.  
K-ASSAY<sup>®</sup> *H. Pylori* Test

		Endoscopic biopsy + rapid urease test		
		Positive	Negative	Total
K-ASSAY <sup>®</sup> <i>H. Pylori</i> Test	Positive	203	1	204
	Negative	13	11	24
	Total	216	12	228

Clinical Sensitivity:  $203/216 = 94\%$

Clinical Specificity:  $11/12 = 92\%$

Total Agreement:  $214/228 = 94\%$

- *H. pylori* ELISA Kit vs. K-ASSAY<sup>®</sup> *H. Pylori* Test

		<i>H. pylori</i> ELISA kit		
		Positive	Negative	Total
K-ASSAY <sup>®</sup> <i>H. Pylori</i> Test	Positive	63	0	63
	Negative	0	4	4
	Total	63	4	67

Clinical Sensitivity:  $63/63 = 100\%$

Clinical Specificity:  $4/4 = 100\%$

Total Agreement:  $67/67 = 100\%$

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