

ICON *H.p*

IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF
ANTI-HELICOBACTER PYLORI ANTIBODY IN
HUMAN WHOLE BLOOD, SERUM OR PLASMA



ICON *H.p* will get your patients up and running again.

ICON *H.p* is your one-step anti-*H. pylori* test.

Blood Banking
Centrifugation
Chemistry
Flow Cytometry
Hematology
Immunoassay
Information Systems
Lab Automation
Molecular Diagnostics
Rapid Diagnostics

ICON *H.p* — One-step anti-*Helicobacter pylori* (*H. pylori*) antibody test utilizes indirect solid-phase immunoassay technology for the qualitative detection of *H. pylori* antibodies.

ICON *H.p* qualitatively detects anti-*H. pylori* IgG antibody in human whole-blood, serum or plasma specimens. This one-step cassette device test is intended to aid in the diagnosis of *H. pylori* infection in adult patients with symptoms of gastrointestinal disorders without costly and invasive procedures. In 10 minutes, you will have accurate diagnostic results to begin your patient's treatment the same day.

- Results in 10 minutes
- Storage at 2-30°C (35-86°F)
- Test uses whole blood or serum/plasma
- Easy, fast and accurate results

PERFORMANCE CHARACTERISTICS

Clinical specimens were collected from 207 symptomatic and asymptomatic individuals who presented for endoscopic examination. Age range was 19-83 years with a mean age of 52 years. Performance characteristics of ICON *Hp* were evaluated by comparison to biopsy/histology, agglutination test and ELISA for detection of anti-*H. pylori* antibody. The results are summarized in the tables.

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TABLE 1. ICON *Hp* VS. BIOPSY/HISTOLOGY

		Biopsy/Histology		
		Positive	Negative	Total
ICON <i>Hp</i>	Positive	71	14	85
	Negative	3	115	118
	Total	74	129	203

When biopsy/histology was used as a reference, the ICON *Hp* test demonstrated 95.9% sensitivity, 89.1% specificity and 91.6% agreement. Four tests were excluded in the calculation due to indeterminate results.

TABLE 2. ICON *Hp* VS. AGGLUTINATION TEST

		Agglutination Test		
		Positive	Negative	Total
ICON <i>Hp</i>	Positive	80	8	88
	Negative	6	113	119
	Total	86	121	207

When the agglutination test was used as a reference, the ICON *Hp* test demonstrated 93.2% agreement.

TABLE 3. ICON *Hp* VS. ELISA

		Biopsy/Histology		
		Positive	Negative	Total
ICON <i>Hp</i>	Positive	78	10	85
	Negative	6	113	118
	Total	84	123	207

When the ELISA was used as a reference, the ICON *Hp* test demonstrated 92.3% agreement.

CLIA

- CPT Code* #86318QW - Whole Blood
#86677 - Serum/Plasma
- Whole Blood - Waived
Serum/Plasma - Moderately Complex



Ordering Information

ICON *Hp* Test Kit 395160

- 30 Test Cassettes
- 35 Capillary Tubes
- 1 Dropper Bottle of Developer Solution containing 0.1% Sodium-Azide

*Exemplar CPT provided. Refer to regional CMS fee schedule for relevant/current CPT codes and reimbursement rates.

Beckman Coulter is the leader in fecal occult blood testing and offers the very best in rapid tests designed to simplify the diagnostic process. Early detection is the single most important advantage a patient can have to survive life-threatening diseases. Beckman Coulter provides the tools and tests physicians need to aid in the diagnosis and management of a variety of disease states.

Beckman Coulter also provides a variety of Immunoassay, Chemistry, Hematology and Centrifugation instruments to aid in the diagnosis and management of a full spectrum of medical conditions. Each system's compact design and cost-effective performance makes it a perfect complement to a physician's office laboratory.

To order product, contact your medical supply distributor. For technical assistance regarding rapid test kits, call Technical Marketing at 800-877-6242 or email askpcd@beckman.com.

Lab Testing Made Easy

Beckman Coulter Rapid Diagnostics Product Offering

Hemoccult

Hemoccult SENA

Hemoccult II SENA elite

Hemoccult ICT

CLIA-waived rapid tests for the detection of hidden blood in feces

Gastrocult

CLIA-waived rapid test for detecting hidden blood in gastric fluid and determining gastric pH

ICON *Hp*

CLIA-waived (whole blood) and moderately complex (serum) rapid test for the detection of antibodies to *H. pylori*

ICON 20 hCG

ICON 25 hCG

CLIA-waived (urine) and moderately complex (serum) rapid tests for the detection of hCG

ICON Mono

CLIA-waived (whole blood) and moderately complex (serum) antibody test for infectious mononucleosis

ICON DS Strep A

ICON SC Strep A

CLIA-waived dipstick and cassette rapid format tests for the detection of Strep A, using throat swab sample



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DS-17653A B2012-13777

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