

## *Helicobacter pylori*

### **Comparison of Commercial Serologic Tests for Diagnosing *Helicobacter pylori* Infection in Korea**

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**Background/Aims:** Various commercial serologic tests have been developed for the diagnosis of *Helicobacter pylori* (*H. pylori*) infection, but clinical data regarding their accuracies are often lacking  
**Methods:** Sixty-four patients who visited Severance Hospital and underwent gastroscopy were enrolled. Multiple biopsy specimens were obtained from antrum and body for histology and rapid urease test (CLO test). As serologic tests, QuickVue, EZ-HP, GAP, Cobas Core II, and Pyloragen tests were used. **Results:** *H. pylori* infection were diagnosed in 40 (62.5%) patients by histology o CLO test. The sensitivities of five serologic tests were as follows: QuickVue, 75.0%; EZ-HP, 90.0% GAP, 85.0%; Cobas Core , 80.0%; Pyloragen test, 80.0%. The specificities of those tests were a follows: QuickVue, 66.7%; EZ-HP, 45.8%; GAP, 62.5%; Cobas Core , 70.8%; Pyloragen, 70.8% The accuracies of them were as follows: QuickVue, 77.5%; EZ-HP, 73.4%; GAP, 85.0%; Cobas Core , 76.6%; Pyloragen, 76.6%. The five serologic tests showed no statistically significant difference in their sensitivity and specificity. The QuickVue and the EZ-HP were comparable in their accuracy. However, the EZ-HP test revealed higher sensitivity and lower specificity than the QuickVue test The GAP test showed better sensitivity compared to those of other quantitative tests, but all of them were comparable in terms of poor specificities. **Conclusions:** The five serologic tests showed lower specificities in Korea than in western countries. Thus, the development of serologic tests with good diagnostic accuracy is necessary in Korea. (**Kor J Gastroenterol 1999;34:582 - 592**)

**Key Words:** *Helicobacter pylori*, Serology, ELISA

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*Helicobacter pylori*( *H. pylori*)  
 가 1997 6 9  
 .1 *H. pylori* 1906  
 Krienitz가 64  
 2 가 가 1983 Mar-  
 shall  
 (curved bacilli)  
 Campylobacter genus  
 proton pump  
 H2  
 bismuth  
 6  
 (種)  
 .3  
 ,  
*H. pylori*  
 46 *H.*  
*pylori* 가  
*H. pylori*  
 hematoxylin-eosin 2  
 Giemsa  
*H. pylori* rapid urease  
 (CLOTM ) (Delta-West Ltd., Bentley, Western  
 Australia) 24  
 가  
 3.  
 QuickVue (Quidel, San Diego,  
 USA), Bio-Rad GAP IgG (Bio-Rad Chemical divi-  
 sion, Richmond, CA, USA), Cobas Core II (Roche  
 products Ltd., Switzerland), Pyloragen (HYCOR Bio-  
 chemical Inc., CA, USA), EZ-HP (Biomerica, Inc.,  
 CA, USA)  
 ELISA (enzyme linked immu-  
 nosorbent assay)  
*H. pylori* IgG  
 QuickVue *H. pylori*  
 30 µl  
 150 µl  
*H. pylori*  
 가 가  
*H. pylori*

IgG 가 H. pylori bead 37 15 H. pylori  
 (alkaline phosphatase) rabbit anti-human peroxidase가 anti-human IgG  
 IgG 가 가 bead -  
 가 .  
 가 5 tetramethylbenzidine hydrogen peroxide가  
 37 15 bead  
 가 H. pylori IgG  
 450 nm  
 EZ-HP 가  
 Pyloragen  
 sample well . 10 100 µl  
 H. pylori 가 20  
 . 3 anti-  
 Bio-Rad GAP IgG ELISA human IgG 100 µl 가 20  
 (strip holder)  
 (microwell strip) IgG , (tetramethyl benzidine) 5  
 10 µl 25 60 . 5 가 450 nm  
 .  
 3 peroxidase가 (Table 1).  
 anti-human IgG 100 µl 가 25 4.  
 30 . 100 µl 가 25 SAS (Statistical Analysis System)  
 10 50 µl 가 450 Receiver operating characteristic analysis  
 nm . ROC  
 Cobas Core II (cut-off value) , ,  
 H. pylori ,

**Table 1.** Basic Mechanism and Composition of Five Serological Tests

Serologic test	Quantitative Test		Qualitative Test		
	QuickVue (Quidel)	EZ-HP (Biomerica)	GAP test (Bio-Rad)	Cobas Core II (Roche)	Pyloragen (Hycor)
Method	ELISA Membrane	ELISA Membrane	ELISA Microplate	ELISA Bead	ELISA Microplate
Dilution	1:6	1:201	1:201	1:41	1:100
Antigen	Purified Ag	Purified Ag	Purified Ag	Purified Ag	Purified Ag
Response time	10 min	10 min	100 min	30 min	45 min
Temperature	RT	RT	RT	RT	RT

Ag, antigen; RT, room temperature.

Chi-square test (6.2%) (Table 2).  
 0.05 rapid urease (CLOM )  
 가  
 , *H. pylori*  
 40 (62.5%) 24 (37.5%)  
 (Table 2).  
 1.  
 64 48 (17-72)  
 21 (34.4%) 43 (65.6%)  
 1:2 .  
 57 (89.1%), 3 (4.7%), 4

**Table 2.** Clinical Characteristics of Subjects

No. of patients	64
Mean age (years)	48 (17-72)
Sex (M:F)	1:2
Endoscopic findings	
Gastritis	57 (89.1%)
Peptic ulcer	3 ( 4.7%)
Gastric cancer	4 ( 6.2%)
<i>H. pylori</i> infection	
Positive	40 (62.5%)
Negative	24 (37.5%)

2.  
 Bio-Rad  
 GAP 12-20 u/ml 20 u/ml  
 12 u/ml .  
 Cobas Core 8-10 u/ml 10  
 u/ml 8 u/ml  
 . Pyloragen 0.88-1.0 u/ml  
 1.0 u/ml 0.88 u/ml  
 .  
 Receiver operating character  
 analysis ROC  
 . Bio-Rad GAP  
 가가 15.1 u/ml ,  
 15.1 u/ml (Fig. 1)  
 Cobas Core 가가 14.7 u/ml  
 , 14.7 u/ml

**Fig. 1.** ROC (receiver operating characteristic) curve analysis for diagnosis of *H. pylori* infection using Bio-RAD GAP tests. Each dot represents respective value according to different sensitivity and specificity. Calculated cut-off value was 15.1 u/ml.

**Fig. 2.** ROC (receiver operating characteristic) curve analysis for diagnosis of *H. pylori* infection using Cobas Core II tests. Each dot represents respective value according to different sensitivity and specificity. Calculated cut-off value was 14.7 u/ml.

**Fig. 3.** ROC (receiver operating characteristic) curve analysis for diagnosis of *H. pylori* infection using Pyloragen test. Each dot represents respective value according to different sensitivity and specificity. Calculated cut-off value was 1.79 u/ml.

(Fig. 2) Pyloragen 가가 1.79 Quick Vue *H. pylori* 가 75.0%, EZ-HP  
 u/ml , 1.79 u/ml 가 90.0%, Bio-Rad GAP 가 85.0%, Cobas  
 (Fig. 3). Core 가 80.0%, Pyloragen 가 80.0% ,  
 Quick Vue *H. pylori* 가 66.7%, EZ-HP  
 3. 가 45.8%, Bio-Rad GAP 가 62.5%, Cobas  
 Core 가 70.8%, Pyloragen 가

**Table 3.** Comparison of Diagnostic Performance of Five Commercial Serologic Tests

	Cut off*	SE (%)	SP (%)	PPV (%)	NPV (%)	Accuracy (%)
Qualitative test						
QuickVue	+/-	75.0	66.7	78.9	61.5	77.5
EZ-HP	+/-	90.0	45.8	73.5	73.3	73.4
Quantitative test						
GAP	15.1	85.0	62.5	79.0	71.4	85.0
Cobas Core II	14.7	80.0	70.8	82.0	68.0	76.6
Pyloragen	1.79	80.0	70.8	82.1	68.0	76.6

\* Cut off Value calculated based on the ROC curve (u/ml); SE, sensitivity; SP, specificity; PPV, positive predictive value; NPV, negative predictive value.

**Table 4.** Comparison of Diagnostic Performance of Three Quantitative Serologic Tests Based on the Cut of Value Suggested by the Manufacturer and Calculated from the ROC Curve

			SE (%)	SP (%)	PPV (%)	NPV (%)	Accuracy (%)	
Manufacture	Excluding	GAP	67.5	70.8	79.4	56.7	68.8	
		borderline	Cobas Core II	85.0	54.2	75.6	68.4	73.4
		value	Pyloragen	92.5	29.2	68.5	70.0	68.8
	Including	GAP	85.0	54.2	75.6	68.4	73.4	
		borderline	Cobas Core II	87.5	54.2	76.1	72.2	75.0
		value	Pyloragen	97.5	20.8	67.2	83.3	68.8
ROC curve	GAP		85.0	62.5	79.0	71.4	85.0	
	Cobas Core II		80.0	70.8	82.0	68.0	76.6	
	Pyloragen		80.0	70.8	82.1	68.0	76.6	

SE, sensitivity; SP, specificity; PPV, positive predictive value; NPV, negative predictive value.

70.8% (Table 4). Pyloragen, 67.5% 85.0%, Cobas Core II  
 Cobas Core II, Bio-Rad GAP, QuickVue, EZ-HP 85.0% 87.5%, Pyloragen 92.5%  
 , Pyloragen, EZ-HP, 97.5% .  
 Bio-Rad GAP, Cobas core II, QuickVue Bio-Rad GAP 가 70.8%  
 . Bio-Rad GAP 가 85.0% 가 54.2%, Cobas Core II 가 54.2%  
 Quick Vue (77.5%), Cobas 54.2%, Pyloragen 가 29.2% 20.8%  
 core (76.6%), Pyloragen (76.6%), EZ-HP (73.4%) (Table 4).  
 (Table 3). 가

(p>0.05).

Bio-Rad GAP 가 68.8%  
 73.4%, Cobas Core II 가 73.4% 75.0%,  
 Pyloragen 가 68.8% 68.8% 가

Bio-Rad GAP

ROC

Evans *H. pylori* n-octyl-glucose  
600,000 MW  
100% 99%

*H. pylori* immunoglobulin G (IgG) IgA  
가

*H. pylori* 가 ELISA  
EZ-HP QuickVue  
Bio-Rad GAP, Cobas Core II  
Pyloragen

IgA IgG 7  
SAS Receiver operating characteris-  
tic analysis ROC

1983 Warren Mar-  
shall *H. pylori* 가 Bio-Rad GAP  
*H. pylori* 20 u/ml, 12 u/ml, 12 u/ml  
*H. pylori* 9 formalin, 20 u/ml (borderline)  
acid glycine 10, 15.1 u/ml  
(agglutination), (complement (Fig. 1). Cobas core II 가  
fixation), ELISA 11-16 10 u/ml, 8  
whole bacteria, crude lysates, u/ml, 8 u/ml 10 u/ml  
partially purified extracts crude antigen 14.7 u/ml  
preparations, 17-20 (Fig. 2). Pyloragen  
1 u/ml, 0.88 u/ml  
(*C. jejuni*, *C. fetus*, *E. coli*) 0.88 u/ml 1 u/ml  
(cross-reactivity) 1.79 u/ml  
가 21-23 (Fig. 3). 가  
가  
acid glycine  
가 21, 24 acid glycine 가  
QuickVue *H. pylori* 75.0%  
66.7%  
29 88.3% 79.4%  
30 84.2% 52.8%

가 25  
가  
21, *C. jejuni*  
(12.5 u/ml)  
*H. pylori* 가 Bio-Rad GAP  
26, 27 93.8-95%, 73.9-  
84.6% 31, 32

85.0%, 62.5%, 가가 가  
 33 72%, 53% .  
 Cobas Core II 80.0% *H. pylori*  
 70.8% 가  
 34 94-100% 87.5-98% .  
 16 74.5% 가  
 98.1% .  
 EZ-HP Pyloragen 가  
 가 *H. pylori*  
 90.0%, 80.0% .  
 45.8%, 70.8% 가 EZ-HP *H. pylori*  
 Pyloragen 100%, 98.6% .  
 96.6%, 96.5% .  
 가 .  
 가 가 : *H. pylori*  
 가 *H. pylori* 가  
 가 .37  
 가 , *H. pylori*가 . : 1997 6  
 9  
 , *H. pylori* 64  
 .  
*H. pylori*가 12 57 , 3 4 .  
 가가  
 가 339 6 CLO *H. pylori*  
 가 .404 ,  
 가 가  
 가 .1923 , QuickVue *H. pylori* , EZ-  
 (intestinal metaplasia) HP , Bio-Rad GAP , Cobas Core ,  
 Pyloragen . : *H. pylori*  
 64 40 (62.5%) 24  
 . QuickVue *H. pylori* 가  
 75.0%, EZ-HP 가 90.0%, Bio-Rad GAP 가  
 85.0%, Cobas Core 80.0%, Pyloragen  
 가 80.0% , Quick Vue *H. pylori*  
 가 66.7%, EZ-HP 가 45.8%, Bio-Rad GAP  
 가 62.5%, Cobas Core 가 70.8%, Pyloragen  
 가 70.8% . : *H. pylori*  
 가



가 ,

*H. pylori*

가

: *Helicobacter pylori*, , ELI-

SA

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