

Helicobacter Pylori (H.Pylori) Antigen Test
(Colloidal Gold)

Diagnostic Sensitivity and Specificity Study Report

Final report date: 2018-02-20

Study Director Signature and Verification Dates

This study meets with the technical requirements of the protocol. The study also meets with technical specification for the test.

Study Director: Li Cheng

Signature: 

Company: Atlas Link Technology Co., Ltd

Position: Head of R & D Department

Verification Dates: 2018-02-20

This summary reviewed the diagnostic performance of Helicobacter Pylori (H.Pylori) Antigen Test from two customers' feedback. Two different conventional methods (respiratory test and rapid urease test (CLO test)) were used as a diagnostic standard for determining whether the patients were infected with HP bacteria. Two immunochromatographic assay tests were also performed, including Helicobacter Pylori (H.Pylori) Antigen Test and a leading commercial HP Antigen Test. The results from Helicobacter Pylori (H.Pylori) Antigen Test were compared with the results provided by either respiratory test and CLO test, or the leading commercial HP Antigen Test.

Customers' information:

Customer's name	Tempharma	Country Medical
Place	Kenya	Uganda
Time period	2014.09 – 2014.12	2014.05 - 2014.10
Lot No.	HP_Ag -540708	HP_Ag -540511
Method used for diagnosis	CLO test	Respiratory test
Sample details of Immunochromatographic assay test	Biopsy specimen	Fecal specimen

The detailed feedback results were listed as below.

The first set of data was from customer “Tempharma”. The patients were diagnosed by CLO test and their biopsy specimens were simultaneously tested by Helicobacter Pylori (H.Pylori) Antigen Test device and a leading commercial HP Antigen Test device. The results from Helicobacter Pylori (H.Pylori) Antigen test were compared to either CLO test or the leading commercial HP Ag test respectively.

Tempharma

		Results of Helicobacter Pylori (H.Pylori) Antigen Test		Subtotal
		Positive	Negative	
CLO test (info. N/A)	Positive	80	7	87
	Negative	0	80	80
Subtotal		80	87	167

Agreement to CLO test: $(80+80)/167 = 95.8\%$

Tempharma

		Results of Helicobacter Pylori (H.Pylori) Antigen Test		Subtotal
		Positive	Negative	
Commercial kit (info. N/A)	Positive	84	0	84
	Negative	3	80	83
Subtotal		87	80	167

Agreement to commercial kit: $(84+80)/167 = 98.2\%$

The second set of data was from customer “Country Medical”. The patients were diagnosed by respiratory test and their fecal specimens were tested by Helicobacter Pylori (H.Pylori) Antigen Test device and a leading commercial HP Antigen Test device. The results from Helicobacter Pylori (H.Pylori) Antigen

test were compared to either respiratory test or the leading commercial HP Ag test respectively.

Country Medical

		Results of Helicobacter Pylori (H.Pylori) Antigen Test		Subtotal
		Positive	Negative	
Respiratory test (info. N/A)	Positive	160	8	168
	Negative	0	60	60
Subtotal		160	68	228

Agreement to respiratory test: $(60+160)/228 = 96.5\%$

Country Medical

		Results of Helicobacter Pylori (H.Pylori) Antigen Test		Subtotal
		Positive	Negative	
Commercial kit (info. N/A)	Positive	148	0	148
	Negative	2	75	77
Subtotal		150	75	228

Agreement to commercial kit: $(148+75)/228 = 97.8\%$

Combined two sets of data together for analysis:

		Results of Helicobacter Pylori (H.Pylori) Antigen Test		Subtotal
		Positive	Negative	
Respiratory test or CLO test	Positive	240	15	255
	Negative	0	140	140
Subtotal		240	155	395

Total agreement to respiratory test or CLO test: $(240+140)/395 = 96.2\%$

		Results of Helicobacter Pylori (H.Pylori) Antigen Test		Subtotal
		Positive	Negative	
Commercial kit (info. N/A)	Positive	235	0	235
	Negative	5	155	160
Subtotal		240	155	395

Total agreement to commercial kit: $(235+155)/395 = 98.7\%$

Conclusion

Performance evaluation and comparison of Helicobacter Pylori (H.Pylori) Antigen Test with reference methods, respiratory test, CLO test (rapid urease test) and a leading commercial HP Ag test were conducted by two different customers in different places. A total of 395 clinic samples were analyzed. For CLO test, the agreement of Helicobacter Pylori (H.Pylori) Antigen Test is 95.8%. For respiratory test, the agreement of Helicobacter Pylori (H.Pylori) Antigen Test is 96.5%. The total agreement is 96.2%. For comparison to a leading commercial HP Ag test, at location one, the agreement is 98.2%; at location two, the agreement is 97.8%; and the total agreement to a leading commercial HP Ag test is 98.7%.