PERFORMANCE OF A NEW LIAISON® *H. Pylori* IgG

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BACKGROUND

Half of the world's population is infected with Helicobacter pylori, and infection can lead to ulcers, gastric cancer, and mucosa-associated lymphoid tissue (MALT) lymphoma. Serology is the only test applicable for large-scale.

AIM

In this study, the performances of a new LIAISON® *H. pylori* IgG assay were evaluated using sera from infected, uninfected by Helicobacter pylori and routine samples.

MATERIALS AND METHODS

Assay

The LIAISON® *H. pylori* IgG assay uses two steps chemiluminescence immunoassay (CLIA) technology for the qualitative determination of specific IgG antibodies to Helicobacter pylori.

Specimens

Two groups of samples have been taken into account, in total 449 were tested :

Group 1: 255 selected samples (114 infected patients with urea breath test reactive and 141 uninfected patients previously tested with urea breath test (UBT) and Enzygnost Anti- H. pylori II/IgG, Siemens Healthcare Diagnostics Germany).

Group 2: 194 unselected samples, submitted to the laboratory for Helicobacter serotesting, were tested by LIAISON® *H. pylori* IgG assay (DiaSorin Saluggia - Italy), a new assay available on totally automatic LIAISON® Analyzer Family.

Immunoblot recomLine Helicobacter IgG (Mikrogen Germany) was used for the confirmation of the presence or absence of IgG anti- *H. pylori* with discrepancies results between LIAISON®, Enzygnost and urea breath test. Sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) were calculated.

RESULTS

Group 1: 255 selected samples (Table I)

	Helicobacter pylori (Urea breath test)	
	Positive	Negative
LIAISON® *H. pylori* IgG	114	141
Positive	109	1**
Negative	5*	140

** 5 negative samples were not confirmed by immunoblot.*

***1 positive sample was not confirmed by immunoblot.*

Five of 114 infected samples and one of 141 uninfected samples were non-reactive and reactive respectively with LIAISON® *H. pylori* IgG assay. These 6 discrepancies samples were confirmed by immunoblot (5 positive and 1 negative samples).

The overall agreement of LIAISON® *H. pylori* IgG with Urea breath test (UBT) was 98%

The specificity and sensitivity of LIAISON® *H. pylori* IgG was 99.32% and 95.6% respectively. The PPV was 99.1% and the NPV was 96.5%.

Group 2: 194 unselected samples (Table II)

	Enzygnost			
LIAISON® *H. pylori* IgG	Positive	Negative	Equivocal	Total
Positive	62	3	1	66
Negative	2	121	2	125
Equivocal	1	2	0	3
Total	65	126	3	194

There were 10 discrepancies results between LIAISON® *H. pylori* IgG and Enzygnost. 4 and 5 samples reactive with LIAISON® and Enzygnost respectively were confirmed by Immunoblot. One sample (reactive with LIAISON® and negative with Enzygnost) was indeterminate by Immunoblot (Table III).

- The overall agreement (equivocal samples excluded) of these 2 assays was 97.3% (183/188) with 96.9% (62/64) and 97.6% (121/124) positive negative agreement respectively.

Interpretation		LIAISON®	Enzygnost	Immunoblot						
	Negative	< 0.8	< 10	Antigen Bands						
	Equivocal	0.8 - 0.9	10 -à 15							
	Positive	≥ 0.9	> 15	Interpretation	CagA	VacA	GroEl	UreA	HcpC	gGT
ID of sample	00585	0.82	<	Negative	-	-	-	-	-	-
	01715	0.86	50	Positive	+	-	-		-	-
	01999	0.3	13	Negative	-	-	-	-	-	-
	03677	2.06	<	Negative	-	-	-	-	-	-
	05590	1.07	<	Indeterminated	-	-	-	-	-	+
	06079	1.20	<	Positive	+	-	-	-	-	-
	22419	0.71	11	Negative	-	-	-	-	-	-
	23951	0.66	17	Positive	+	-	-	-	-	-
	29456	0.88	<	Positive	+	-	-	-	-	-
	03014	0.6	18	Positive	-	-	+	-	-	-

Table III: Results of 10 discrepancies samples by Immunoblot.

CONCLUSION

LIAISON® *H. pylori* IgG is the fully-automated and high-throughput immunoanalyzer for the *H. pylory* IgG serology and showed, in this study, a good overall agreement 98% with Urea breath test (UBT) and the performance parameters specificity, sensitivity, positive predictive value and negative predictive value are > 95%.
In combination with clinical or biochemical data, this test can be used in initial diagnosis of Helicobacter pylori infection or in special clinical situations where a small amount of bacteria colonize the stomach (digestive hemorrhage, gastric atrophy, gastric lymphoma MALT, gastric cancer).

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