Performance of a new LIAISON® H. pylori IgG

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.

**Background**

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 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.

**Results**

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%.

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).

**Conclusion**

LIAISON® H. pylori IgG is the fully-automated and high-throughput immunoanalyzer for the H. pylori IgG serology and showed, in this study, a good overall agreement 98% with Urea breath test (UBT) and the performance parameters specificity, 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).