

## Detection of *Helicobacter Pylori* Infection by Imported IgG ELISA Kits in Comparison with Iranian Home Made Kit

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### ABSTRACT

#### Background

*Helicobacter pylori* (Hp) is a gram negative, spiral shaped bacterium which colonizes the gastric mucosa and induces gastroduodenal complications varying from mild gastritis with no clinical complications to peptic ulcer diseases and even gastric malignancies. The rate of Hp infection is 30-50% in developed countries whereas it has been rated up to 80% of the adult population in developing countries like Iran.

Hp infection can be detected by various diagnostic methods. Culturing biopsy specimens and Rapid Urease Test (RUT) are the most common and reliable tests which can manifest Hp infection through proper sampling but these methods are invasive ones due to the need for endoscopy procedure in isolation of biopsy specimen. Application of serological assays are being increasingly used for epidemiological studies and detecting systemic immune responses toward past Hp infection. ELISA assays are the most popular techniques particularly in cases with no previous treatment.

#### Materials and Methods

In this study we tested three imported IgG ELISA kits which are available for clinical diagnostics in detecting host sero-reactivity to Hp infection and compared them with a home made IgG ELISA kit. Histology and RUT were used as the gold standard tests for determination of Hp positive vs. Hp negative subjects using biopsy specimens from antrum. Sensitivity, specificity, accuracy and other required criteria were evaluated for each ELISA kit.

#### Results

According to the results the original criteria (Sensitivity and specificity) for each kit were as follows: BIOHIT (41.6%, 100%), Trinity (100%, 86.6%), Pishtaz (100%, 86.6%), Home made (100%, 92.6%).

#### Conclusions

Evaluation of these different IgG ELISA kits originating from different parts of the world and cross comparison of the results indicated that the cut off values should be refined for user country in order to obtain the highest sensitivity and specificity. These differences can be due to the vast geographic heterogeneity among Hp antigens. Furthermore, this study showed that home made ELISA kit can be substituted for imported ELISA kits due to its valid serological criteria.

**Keywords:** *Helicobacter pylori*, IgG ELISA, Serology, Screening

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### BACKGROUND

*Helicobacter pylori* (Hp) infects more than half the world adult population and is one of the rare