DEVELOPMENT OF A NEW BIOCHIP ASSAY FOR THE QUANTITATIVE DETECTION OF ANTIBODIES TO *HELICOBACTER PYLORI*

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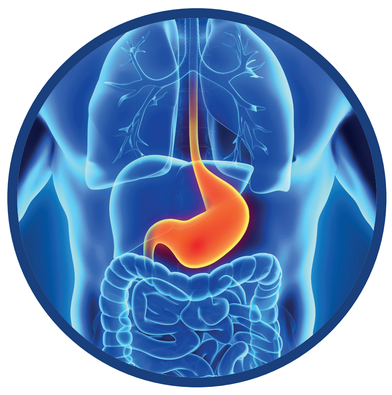
Introduction

Helicobacter pylori infection is the most common cause of atrophic gastritis and is associated with a higher risk of developing gastric carcinoma. Effective monitoring is a challenge as the majority of patients positive for *H. pylori* are asymptomatic. Therefore, the development of a fast, non-invasive screening tool that provides an accurate profile on the condition of the patient's stomach mucosa is essential.

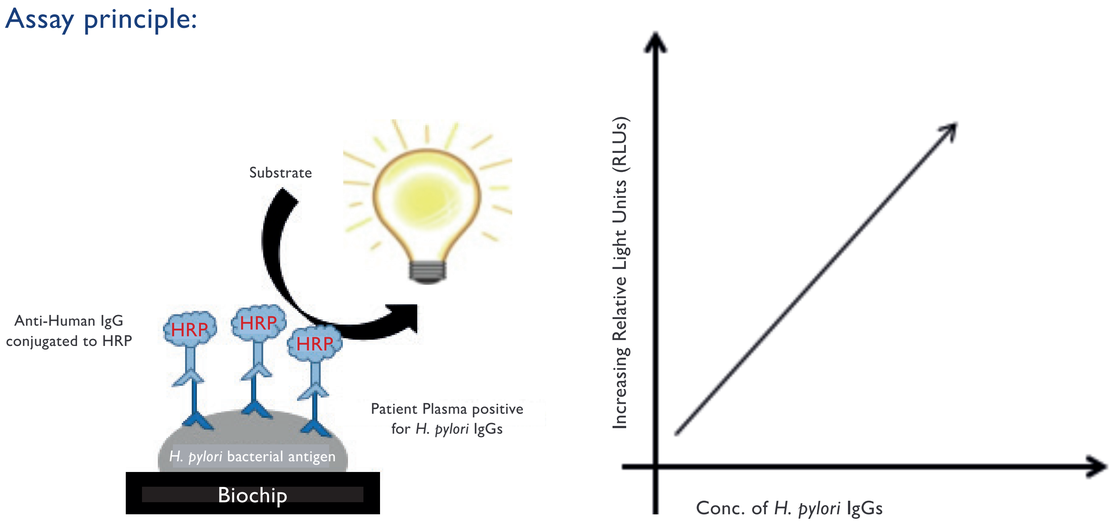
Enzyme-Linked Immunosorbent Assays (ELISA) have been developed for the individual detection of *H. pylori* antibodies, Gastrin-17 (G17), Pepsinogen I and II (PGI & PGII) in plasma. (GastroPanel, Biohit Oyj, Helsinki, Finland). With the aim to provide a comprehensive profile of the stomach mucosa using Biochip Array Technology (BAT), the present collaborative study reports the development of a new biochip assay for the quantitative detection of *H. pylori* antibodies which will be used in combination with the previously reported multiplex biochip array of PGI, PGII and G17.



Methodology

H. pylori antigen was immobilised on the biochip surface defining a discrete test site. An indirect sandwich chemiluminescent immunoassay, applied to the biochip analyser Evidence Investigator, was used for detection of *H. pylori* antibodies. A correlation study was carried out on a cohort of 338 plasma samples between this biochip assay and the ELISA (Biohit Oyj, Helsinki, Finland).

Assay principle:



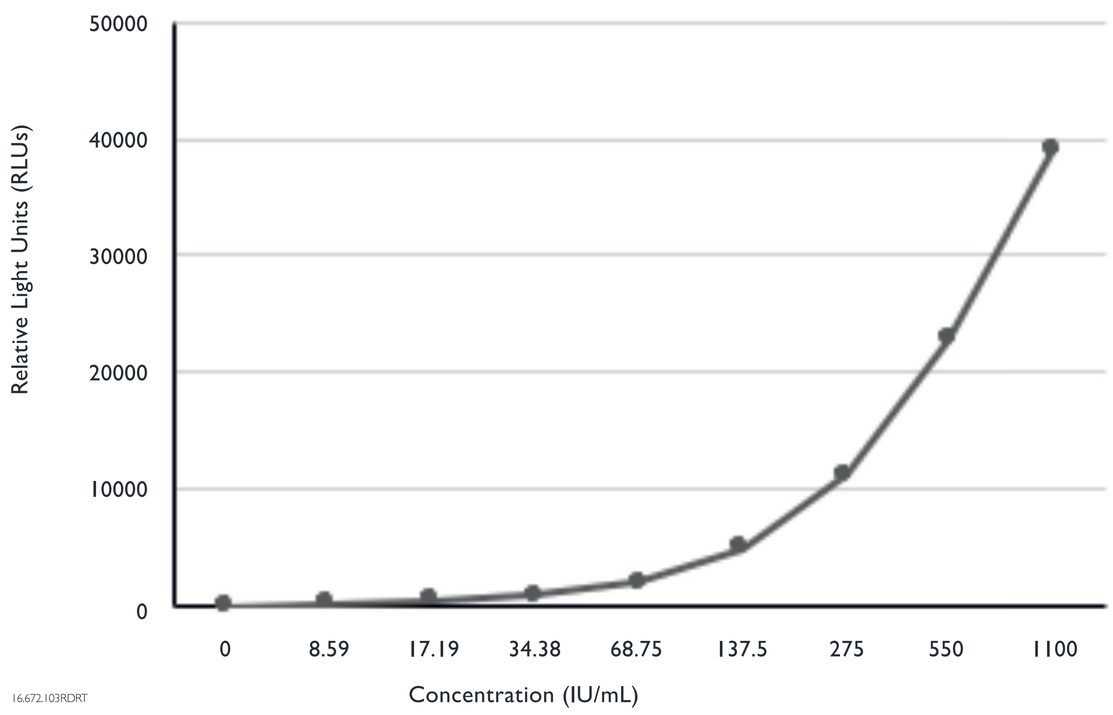
Conclusion

Results show excellent analytical performance of the newly developed biochip assay for the quantitative determination of *H. pylori* antibodies from plasma samples. This test offers a new non-invasive screening tool for atrophic gastritis and those at risk of gastric cancer as well as a method to monitor *H. pylori* eradication therapy. When used in combination with the previously reported three-plex Gastropanel Array (PGI, PGII and G17), it will provide a comprehensive profile on the stomach mucosa. Further application to the automated random access analyser Evidence Evolution will ensure reliable high throughput analysis and enable large scale population screening.

Results

The assay presented a functional sensitivity value of 4.7 IU/mL (assay range 0-1100 IU/mL).

H. pylori assay: typical standard curve



16.672.103RDRT

Intra-assay precision (n=20)		
Sample	Concentration (IU/mL)	CV (%)
Sample 1	24.1	8.8
Sample 2	75.6	6.2
Sample 3	442.9	8.6

16.617,618,652,759,763.103RDRT

Inter-assay precision (n=20)		
Sample	Concentration (IU/mL)	CV (%)
Sample 1	15.6	10.1
Sample 2	43.7	7.4
Sample 3	292.1	10.9

16.815-819,823-828.103RDRT

Sample Assessment

Assessment of 338 plasma samples using the biochip assay and the ELISA indicated overall concordance of 95.3% and the regression analysis showed a correlation coefficient of 0.85.

Sample agreement: biochip assay vs ELISA	
Agree =	322
Disagree =	16
Overall Concordance (%) =	95.3
Average Bias (%) =	5.5
Slope =	1.15
Correlation coefficient =	0.85

16.737,741,771,773,783,785,797,800.103RDRT