

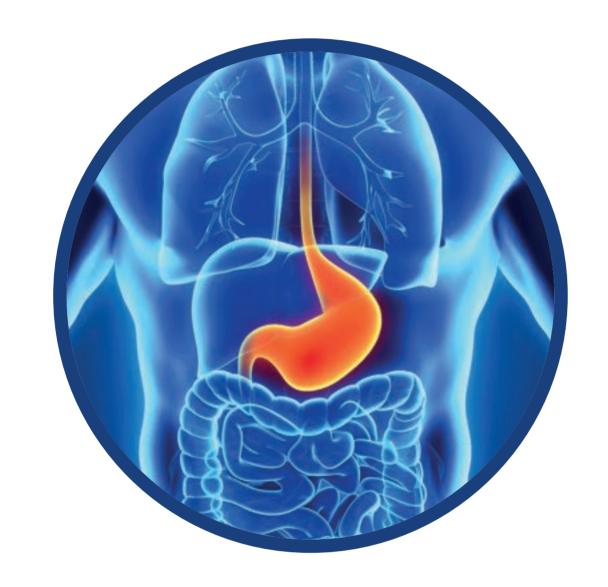
# DEVELOPMENT OF A NEW BIOCHIP ASSAY FOR THE QUANTITATIVE DETECTION OF ANTIBODIES TO HELICOBACTER PYLORI

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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.

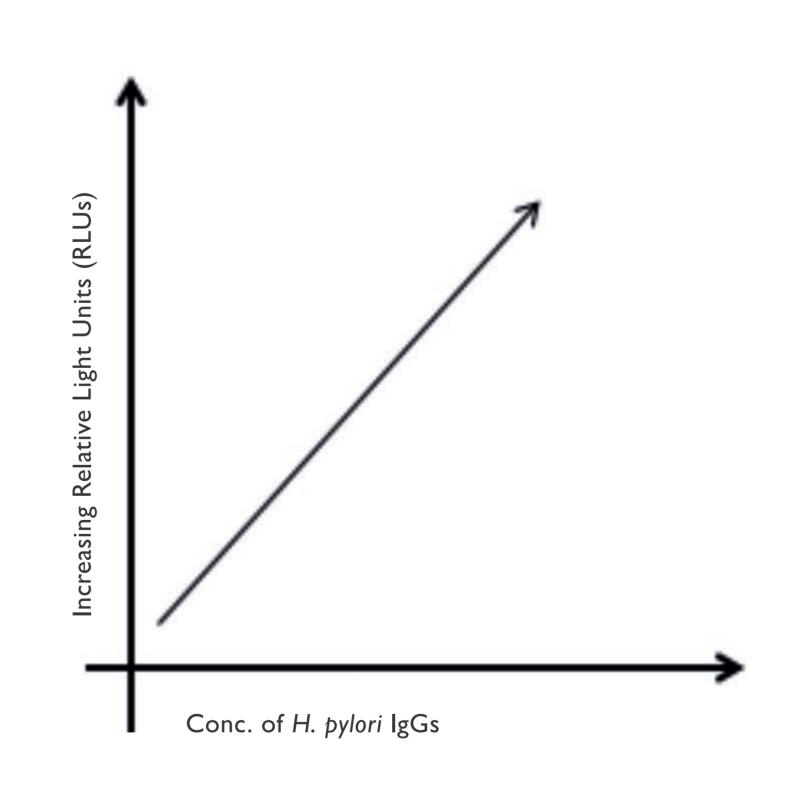
Enzyme-Linked Immunosorbent Assays (ELISA) have been developed for the individual detection of *H. pylori* antibodies, Gastrin-17 (G17), Pepsinogen I and II (PGI & PGII) in plasma. (GastroPanel, Biohit Oyj, Helsinki, Finland). With the aim to provide a comprehensive profile of the stomach mucosa using 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).

# Anti-Human IgG conjugated to HRP Anti-Human IgG conjugated to HRP Patient Plasma positive for H. pylori IgGs H. pylori bacterial antigen Biochip



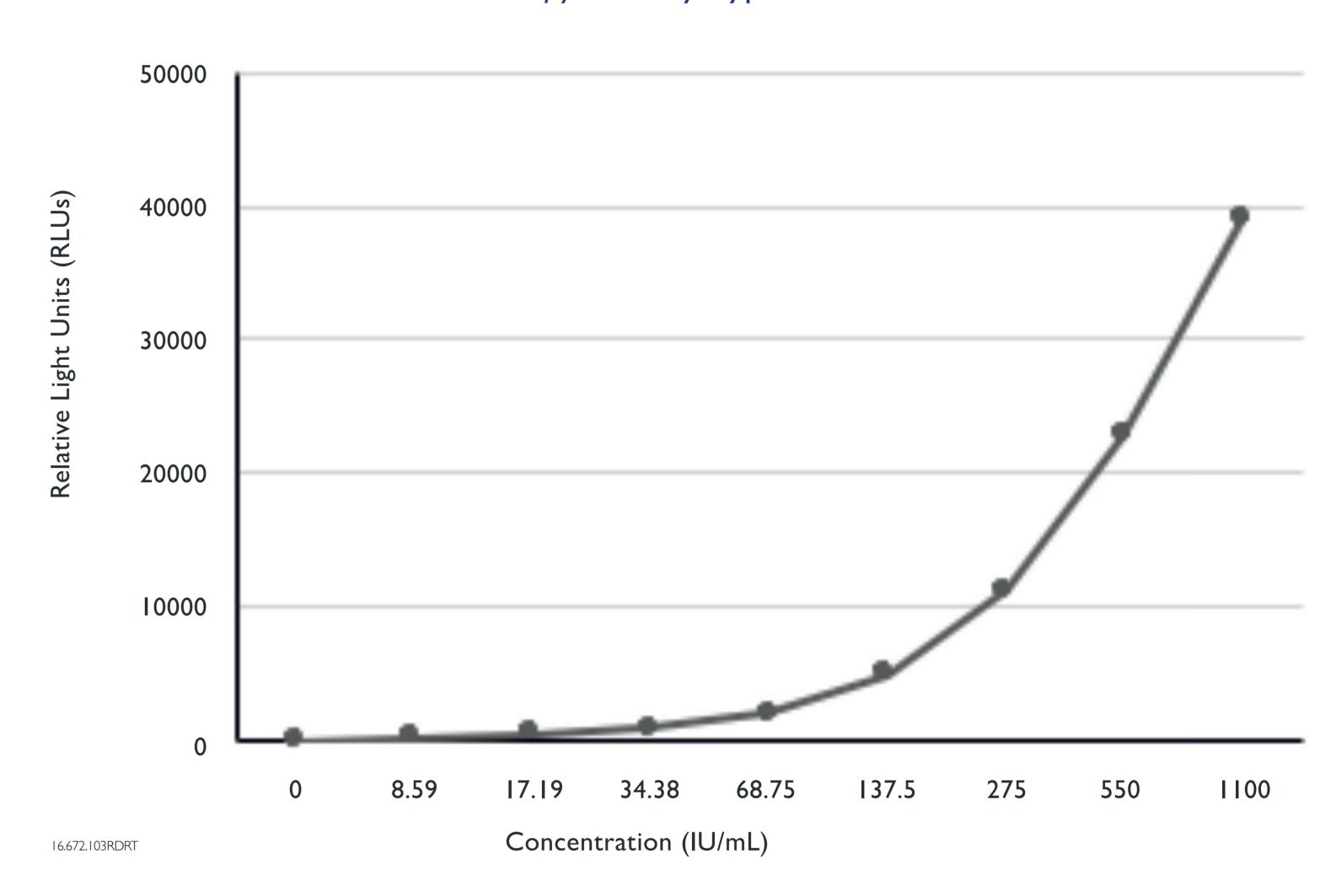
# Conclusion

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



	Intra-assay precision (n=20)	
Sample	Concentration (IU/mL)	CV (%)
Sample I	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 I	15.6	10.1	
Sample 2	43.7	7.4	
Sample 3	292.1	10.9	
14.815.819.823.828.103BDBT			

### 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