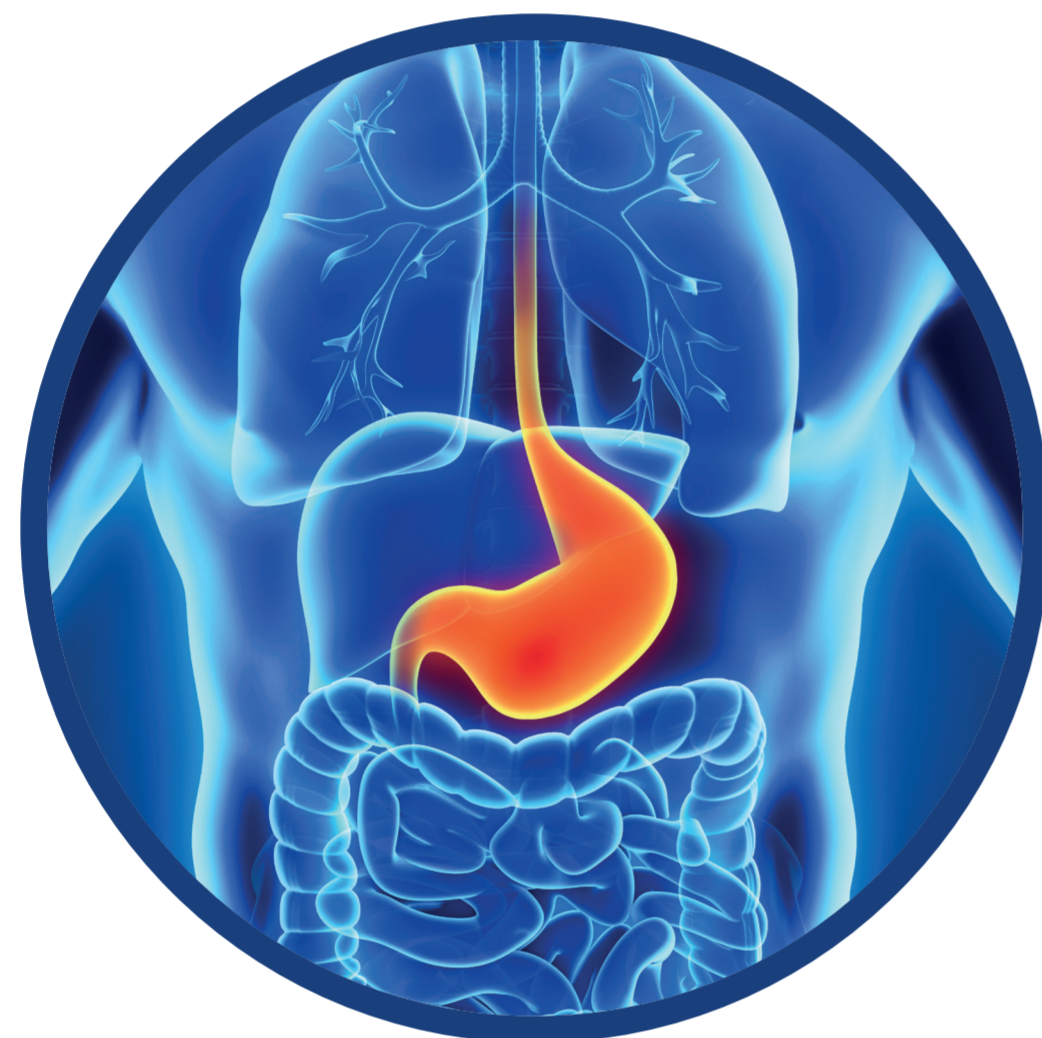


## Introduction

*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.

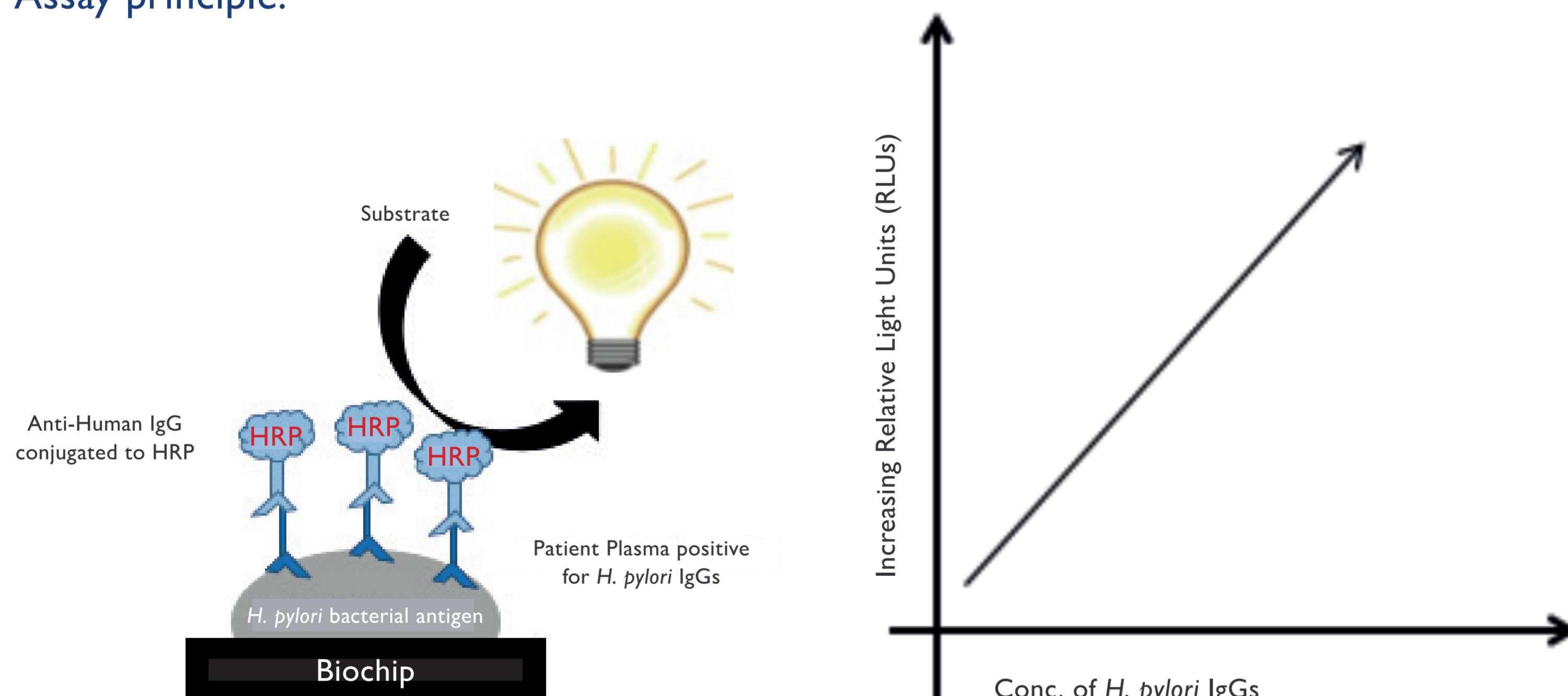
Enzyme-Linked Immunosorbent Assays (ELISA) have been developed for the individual detection of *H. pylori* antibodies, Gastrin-17 (G17), Pepsinogen I and II (PGI & PGII) in plasma. (GastroPanel, Biohit Oyj, Helsinki, Finland). With the aim to provide a comprehensive profile of the stomach mucosa using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



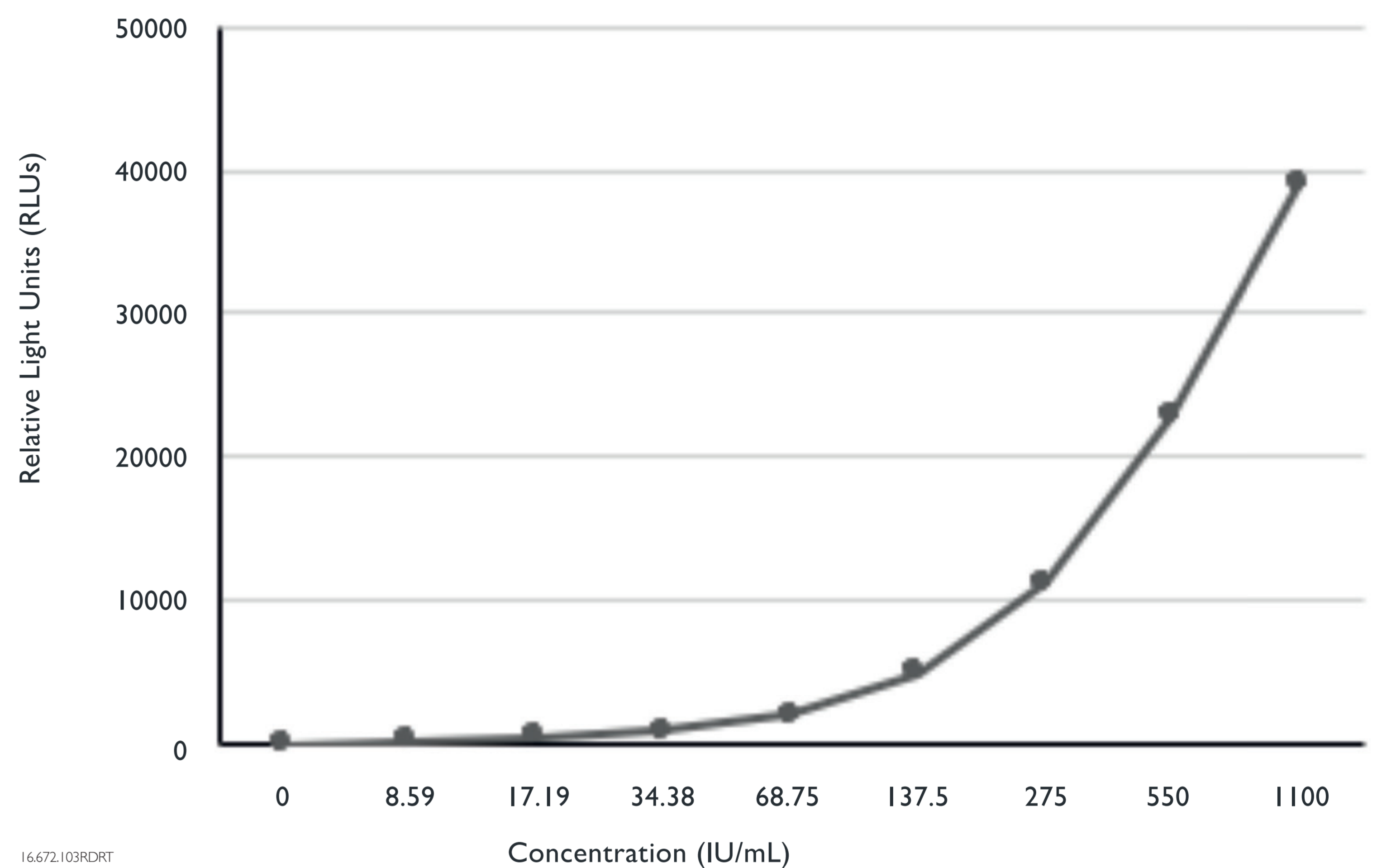
## Conclusion

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



### 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

### 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

### 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