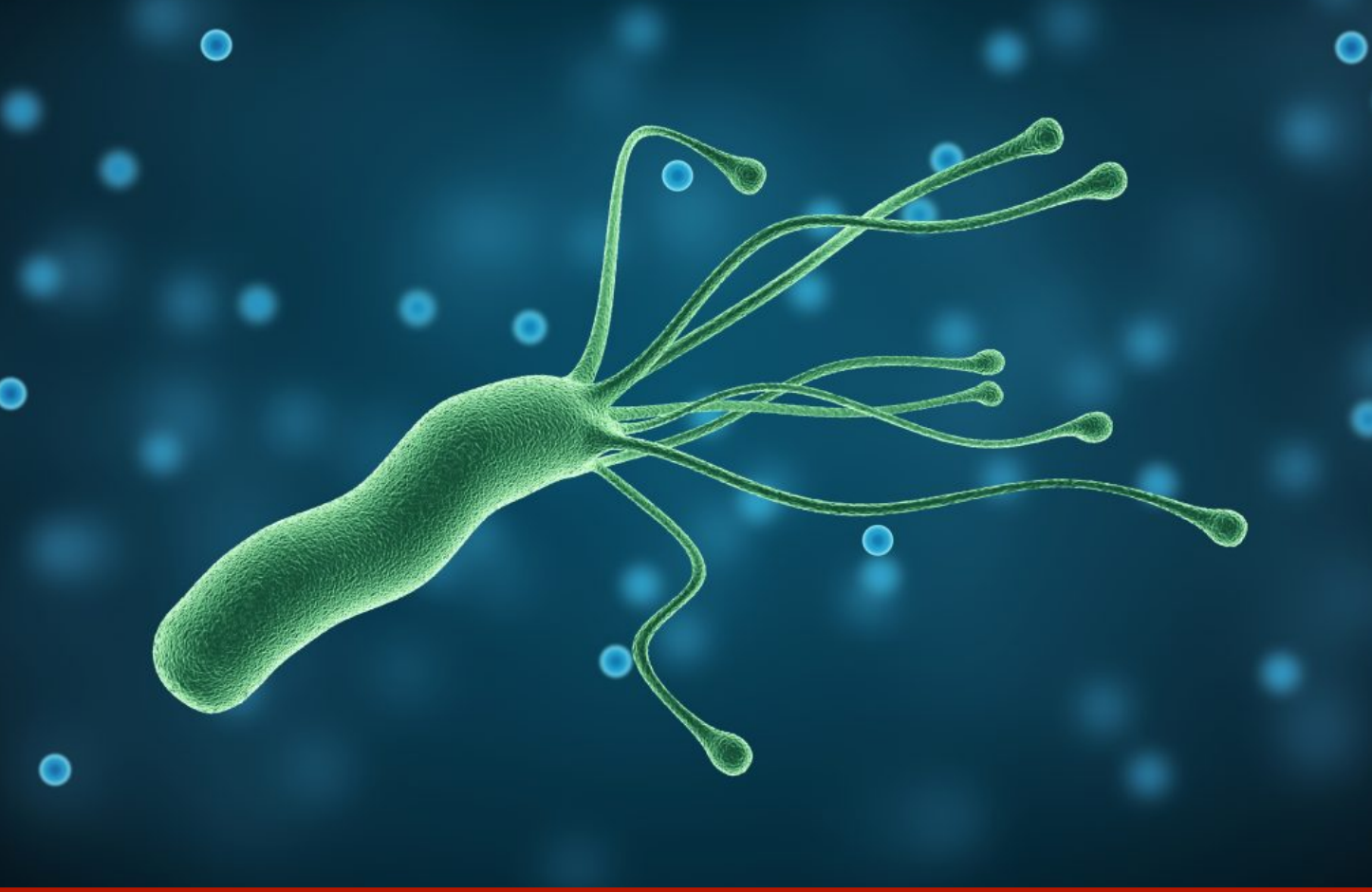

DiaSino® H.Pylori IgG test

Quantitative ELISA assay for specific and accurate antibody detection of Helicobacter Pylori

diasino®

DiaSino® H.Pylori IgG testing

What you need to know about H.Pylori

Helicobacter pylori is one of the most common bacterial infections in humans, affecting nearly **50% of the global population**[1]. H.pylori has been associated with the development of serious upper **gastrointestinal** (GI) conditions including **chronic gastritis, peptic ulcer disease, gastric cancer**[2], and **mucosa-associated lymphoid tissue** (MALT).

A **serological test** has been the **first choice** for the detection of H. pylori infection because it is easy to perform compared to the more invasive diagnostic tests. A positive serologic test indicates the presence of H. pylori antibodies that confirms both a possibility for **past infection** or **potential current infection**.

DiaSino® quantitative detection of IgG antibody to H.Pylori

A total of 877 serum samples, prospectively collected from subjects sent to laboratory for H. pylori IgG testing, were tested by the DiaSino® H. pylori IgG assay and a reference H. pylori IgG assay. Results are summarized in the table below:

Optical agreement with Reference assay				
DiaSino H.Pylori IgG	**Reference assay**			**Total**
	Positive	Equivocal	Negative	
Positive	361	9	5	375
Equivocal	2	4	3	9
Negative	8	6	479	493
Total	371	19	487	877

Positive agreement	(361/371) 97.3%	95% CI (95.8-98.4)
Negative agreement	(479/487) 98.4%	95% CI (96.6-99.1)
Overall agreement	(844/877) 96.2%	95% CI (94.3-97.7)

DiaSino® H.Pylori IgG test characteristics

Testing time	:	70 minutes
Test principle	:	Indirect quantitative
Calibrators	:	0, 10, 25, 50, 100, 150 U/mL* (*DiaSino reference value)
Sample material	:	Serum/Plasma
Sample volume	:	100 µL
Detection limit	:	0.2 U/mL
Measuring range	:	0.2-150 U/mL
Traceability	:	Standardized against a reference assay
Expected value	:	>20 U/mL

References

1. Goh K-L, Chan W-K, Shiota S, Yamaoka Y. Epidemiology of Helicobacter pylori Infection and Public Health Implications. Helicobacter 2011;16(Suppl. 1):1–9.
2. Malfertheiner P, M_egraud F, O'Morain C, Kuipers E, Bazzoli F, EL-Omar E, Graham D, Hunt R, Rokkas T, Vakil N, the European Helicobacter Study Group. Current concepts in the management of Helicobacter pylori infection. The Maastricht-32005 Consensus Report. Gut 2007;56:772–81.

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