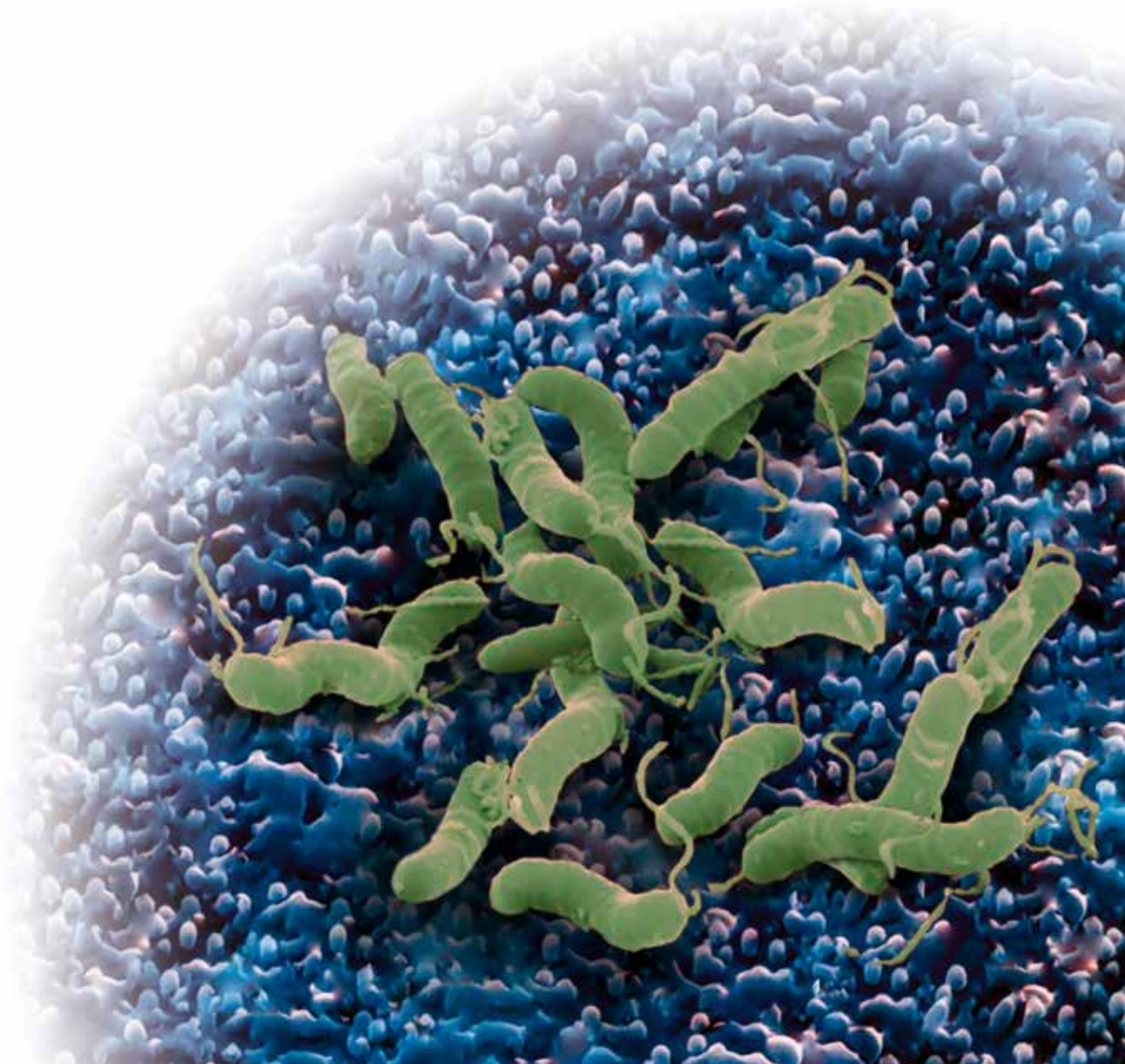


Stool testing

LIAISON® *H. pylori* SA

The fully automated solution for fast *H. pylori*
Stool Antigen detection



DiaSorin

The Diagnostic Specialist

FOR OUTSIDE THE US AND UK ONLY

Stool testing

LIAISON® *H. pylori* SA

Helicobacter pylori is a spiral shaped bacterium, living in the mucus of the human digestive tract and is present in half of the world population.

Strongly associated with peptic ulcer disease and chronic active gastritis, *H.pylori* is a major risk factor for gastric adenocarcinoma.

Diagnosis of infection can be achieved by non-invasive methods, such as detection of *H.pylori* antigens in stool sample. The *H.pylori* stool antigen assay provides a simple alternative to the urea breath test and is appropriate for diagnosis and follow-up of infection.

■ Key Assay features

Number of tests	50	Sample type	Stool
Method	Sandwich Qualitative	Throughput	90 results / hour
Solid Phase	Monoclonal Antibodies to faecal antigens	Time to first result	30 minutes
Conjugate	Monoclonal Antibodies to faecal antigens	Integral on board stability	8 weeks
Label	ABEI	Calibrators availability	2 lyophilized
Sample volume	200 µL	Calibration stability	2 weeks

■ Performance Characteristics

A total of 201 stool samples from symptomatic patients were tested by LIAISON® *H.pylori* SA assay and a commercial *H.pylori* Stool Antigen EIA assay.

LIAISON® <i>H.pylori</i> SA	Commercial EIA assay		
	Positive	Negative	Total
Positive	96	3	99
Negative	3	99	102
Total	99	102	201

Positive agreement	97.0%	95% CI (91.5-99.0%)
Negative agreement	97.1%	95% CI (91.7-98.9%)
Overall agreement	97.0%	95% CI (93.6-98.6%)

A total of 60 follow-up stool samples from infected symptomatic patients were tested by LIAISON® *H.pylori* SA assay and a commercial *H.pylori* Stool Antigen EIA assay, four weeks after completion of eradication therapy.

LIAISON® <i>H.pylori</i> SA	Commercial EIA assay		
	Positive	Negative	Total
Positive	2	2	4
Negative	0	56	56
Total	2	58	60

Positive agreement	100.0%	95% CI (29.2%-99.2%)
Negative agreement	96.6%	95% CI (88.3%-98.9%)
Overall agreement	96.7%	95% CI (88.7-99.0%)

■ Ordering information

LIAISON® *H.pylori* SA (code 318920)

LIAISON® *H.pylori* SA Control set (code 318921)

Product availability subject to required regulatory approvals



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