Stool testing

LIAISON® Meridian *H. pylori* SA

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

DiaSorin

The Diagnostic Specialist

FOR OUTSIDE THE US AND CANADA ONLY

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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 an aid in diagnosis of suspected infected patients and to measure post therapy response.

Key Assay features

Number of tests	100
Method	Qualitative, one-step sandwich
Solid Phase	Monoclonal Antibody to faecal antigens
Conjugate	Monoclonal Antibody to faecal antigens
Label	ABEI
Sample volume	200 µL extracted sample

Sample type	Stool
Throughput	90 results / hour
Time to first result	30 minutes
Integral on board stability	8 weeks
Calibrators availability	2 lyophilized
Calibration stability	4 weeks

Performance Characteristics

A total of 277 stool samples from symptomatic patients were tested by LIAISON® Meridian *H. pylori* SA assay to the established composite reference method, considered to be endoscopic biopsy and histopathological examination and the UBT (urea-breath-test).

Tab 1:

	Comparator Composite Reference Method		
LIAISON® Meridian *H. pylori* SA	Infected	Not Infected	Total
Positive	64	3	67
Equivocal	0	0	0
Negative	3	207	210
Total	67	210	277

			95% Confidence Interval
Clinical Specificity	207/210	98.6%	95.9-99.7%
Clinical Sensitivity	64/67	95.5%	87.5-99.1%

A prospective study consisting of 8 subjects undergoing evaluation of post therapy response was performed to compare the LIAISON® Meridian *H. pylori* SA assay to the established composite reference method and urease detection test.

			95% Confidence Interval
Clinical Sensitivity	8/8	100%	63.1-100%

Ordering information

LIAISON® Meridian *H. pylori* SA (code 318200)	LIAISON® Meridian *H. pylori* SA Control set (code 318201)

Product availability subject to required regulatory approvals

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