ISE S.r.l.
CUSTOMISED SOLUTIONS FOR YOUR LABORATORY

EN

H.pylori

REF R33300000057

R1 1x 18.3mL | **R2** 1x 1.8mL

Instructions For Use

100 Tests

Doc Control: R33300000057_**1.1A.E**

CE

IVD

Intended Use

H.pylori is a latex turbidimetric assay only for the quantitative detection of Helicobacter pylori antigen inhuman stool samples and is intended for use on the I.S.E. S.r.l. **Hemo One** analyser.

For professional in vitro diagnostic use only.

Diagnostics Application

H.pylori is a spiral-shaped bacterium, found in the gastric mucous layer or adherent to the epithelial lining of the stomach. H. pylori causes more than 90% of duodenal ulcers and up to 80% of gastric ulcers.
The importance of Helicobacter pylori testing has increased greatly since the strong correlation between the presence of bacteria and confirmed gastrointestinal diseases (stomach and duodenum) like gastritis, peptic ulcer disease and gastric carcinoma.

Method

H.pylori latex turbidimetric assay is based on agglutination reactions. These involve in vitro aggregation of microscopic latex particles. This aggregation consists in the specific reaction between antigen and antibodies, antigen contained in the sample and the antibodies anti-antigen coated on polystyrene latex particles. The sample is mixed with a suspension containing antibodies against the antigen bound to latex particles. If antigen is present in the sample it will react with the antibodies and form an aggregate. If no antigen is present in the sample the mixture will keep its appearance as a smooth suspension. Such turbidity is measured as an increase in absorbance at the determinate wave and is proportional to the quantity of antigen contained in the sample.

Reagents Provided

R1	**Reagent 1**:	1 Vials x 18.3 mL	Ready to Use
R2	**Reagent 2**:	1 vials x 1.8 mL	Ready to Use

Stability and Storage

The reagents are stable until expiry date on the label when stored at 2-8°C. DO NOT FREEZE
After opening the reagents are stable for 1 month at 2-8°C.

Reagents required but not supplied.

Reference	Description
R3330000063	H.pylori Stool Extraction Vials
R3330000066	Standard Set H.pylori
R3330000070	Control Set H.pylori

Sample collection and preparation

Samples should be collected utilising the H.pylori Stool Extraction Vials. Homogenize stool samples as thoroughly as possible prior to preparation.

- R3330000063 H.pylori Extraction Vials

Consult the H.pylori Stool Extraction Vial instructions for use for correct stool sample extraction.

The samples can be stored in the refrigerator (2-8°C) for 7 days prior to testing.

ASSAY PROCEDURE

Application parameters

The Application parameters are included in the Hemo One software. In the event of a missing the H.pylori protocol please contact your authorised ISE representative.

Any application not explicitly approved by I.S.E. S.r.l. cannot be guaranteed in terms of performance.

Hemo One Use

Consult the I.S.E. S.r.l. Hemo One user manual for instructions on the proper use of the analyser.

Material Preparation

- Ensure samples are collected correctly in accordance with the sample preparation procedure.
- Allow reagents and stool samples to reach room temperature (15-30°C) prior to testing.
- Allow any calibrator or control material to reach room temperature (15-30°C) prior to testing.

Calibration curve establishment

A calibration curve must be performed prior to running samples. The curve must be validated with controls.

Calibration Stability

The calibration is recommended to be run every 7 days on the Hemo One analyser.

Quality control

For quality control purposes only use the following materials:

- R3330000070 Control Set H.Pylori

Concentration is indicated on the label of the vial. The use of control materials at two different concentrations is recommended in order to verify test precision across the measuring range. Control frequency should be run in accordance with the laboratory's quality management system.

If the obtained results are out of the tolerance range;
- Ensure all materials are not expired
- Ensure all materials have been stored and prepared correctly
- Perform a calibration

In the event of controls results not meeting the defined tolerances please contact you local ISE authorised representative for support.

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ANALYTICAL CHARACTERISTICS / PERFORMANCE

Results
The results are evaluated automatically by the Hemo One and presented in **ng/mL** (ng H. pylori antigen/mL)

NORMAL VALUES

- Negative < 0.5 ng/mL
- Grey Zone: Between 0.5 and 1 ng/mL.
- Positive results: >1 ng/mL.

Results between 0.5 and 1 ng/mL are between the detection and quantification limit. A second sampling is recommended to clarify the diagnosis. In case, the second result also shows a value in this range, the recommendation is to follow up the patient some time later.

Positive results determine the presence of H. pylori in human stool samples

Method Comparison
An evaluation was performed comparing ISE H.pylori to an immunochromatographic test (CerTest H. pylori, CerTest). The results were as follows:

	Sensitivity	Specificity
ISE H.Pylori vs certes H.Pylori	**88%**	**> 98%**

Linearity
Using the calibrator kit the H.Pylori kit is linear in the calibration range of **1-40 ng/mL**

Limit of detection (LOD):
Limit of detection (LOD): **0.5 ng/mL**
The lower limit of detection was determined on 20 samples and 2 sample replicates as the mean value + 2 SD

Limit of quantification (LOQ):
Limit of quantification (LOQ): : **1 ng/mL.**
The lower limit of quantification is defined as the lowest actual amount of analysis that can be reliably detected; imprecision is < 20% as CV%

Precision
Precision was assessed with 3 different controls

Precision	Low	Medium	High
Number	20	20	20
Mean (ng/mL)	2.6	10.3	36.7
SD	0.2	0.4	0.6
CV (%)	8	4	2

Prozone effect
Studies have been made up to a concentration of 2 µg of anti-H. pylori antigen/mL and no false negative results have been observed.

Disposal of reagent
Disposal of reagents must be performed in accordance with the EC regulations regarding waste, or the local national or regional legislation.

The product is in conformity with D.L: 8 September 2000, no. 332 "Actuation of the directive 98/79/EC regarding in vitro medical diagnostic devices".

Symbols on labels and packaging

IVD	In vitro diagnostic medical device
REF	Catalog Number
LOT	Lot or batch number
	Manufacturer
	Expiry date
	Temperature limitation
	Consult Instructions for use

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