

VIASURE MULTIPLEX

H. pylori + Clarithromycin resistance Real Time PCR Detection Kit

Pathogen and product description

The genus *Helicobacter* belongs to the family Helicobacteriaceae of the order Campylobacterales. *Helicobacter pylori* (*H. pylori*) is a gram-negative microaerophilic spiral-shaped bacterium, which is able to colonize the mucus layer of the human stomach and the upper part of small intestine (duodenum).

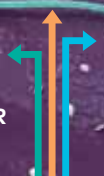
More than half of the world population is estimated to be infected with *H. pylori*, but most individuals are asymptomatic. The new infections might be due to direct person-to-person transmission, via either an oral-oral, fecal-oral route or both. Nevertheless, the role of coccoid form of *H. pylori* as a vehicle of infection from food and water sources should not be discarded. *H. pylori* is involved in the pathogenesis of atrophic gastritis, gastroduodenal ulcer, gastric cancer and gastric mucosa-associated lymphoid tissue (MALT) lymphoma.

At present, several diagnostic assays for *H. pylori* detection are available and grouped as “invasive” or “noninvasive”, but none of them can be considered as gold standard alone. Invasive methods include histology, culture and rapid urease testing, which require gastric biopsy specimens obtained by gastroduodenoscopy. Noninvasive approaches include fecal antigen detection, serologic testing, and urea breath testing among others.

Urease is an important factor for the maintenance and virulence of the bacterium in the gastric mucosa. It is composed of two structural subunits encoded by genes, *ureA* and *ureB*, which have been frequently employed as target genes for the specific detection of *Helicobacter pylori*.

Clarithromycin is a bacteriostatic antibiotic mostly used in childhood to treat upper and lower respiratory tract infections, but, its application to treat *H. pylori* is the most used indication. The main action mode of clarithromycin as one of the wide-spectrum antibiotics used in *H. pylori* therapy is to prevent protein translation. Following the first exposure to the clarithromycin, spontaneously mutations (in both 23S rRNA operons) confer *H. pylori* resistance genotype and phenotype. The direct impact of these mutations is emergence of *H. pylori* strains resistant to clarithromycin. To now, two major mutations A2142G and A2143G were listed as main cause of antibiotic resistance in clinical isolates.

VIASURE *H. pylori* + Clarithromycin resistance Real Time PCR Detection Kit is designed for the diagnosis of *H. pylori*, Clarithromycin resistance and Clarithromycin wild-type sequence in the 23S rRNA in human stool samples and gastric tissue biopsies.



Analytical sensitivity

VIASURE *H. pylori* + Clarithromycin resistance Real Time PCR Detection Kit has a detection limit of ≥ 10 DNA copies per reaction for Clarithromycin resistance and *H. pylori* (Figures 1, 2 and 3).

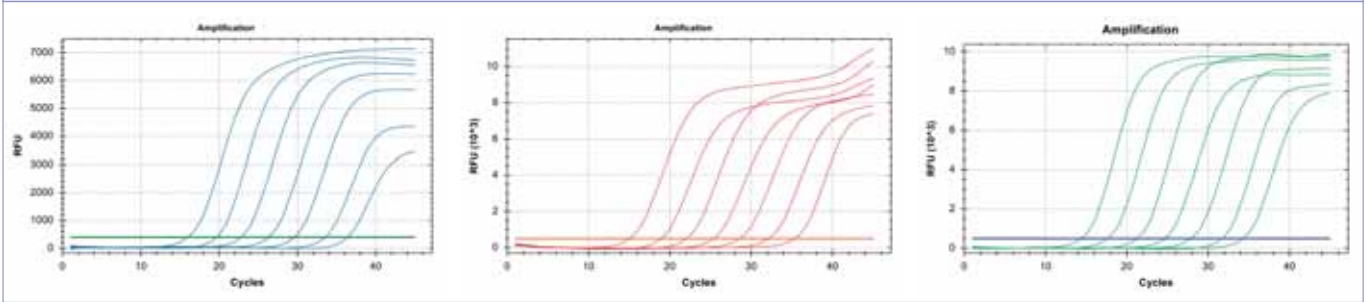


Figure 1. Dilution series of Clarithromycin resistance (10^7 - 10^1 copies/rxn) template run on the Bio-Rad CFX96TM Real-Time PCR System (channel FAM).

Figure 2. Dilution series of *H. pylori* (10^7 - 10^1 copies/rxn) template run on the Bio-Rad CFX96TM Real-Time PCR System (channel ROX).

Figure 3. Dilution series of Clarithromycin wild-type sequence (10^7 - 10^1 copies/rxn) template run on the Bio-Rad CFX96TM Real-Time PCR System (channel HEX).

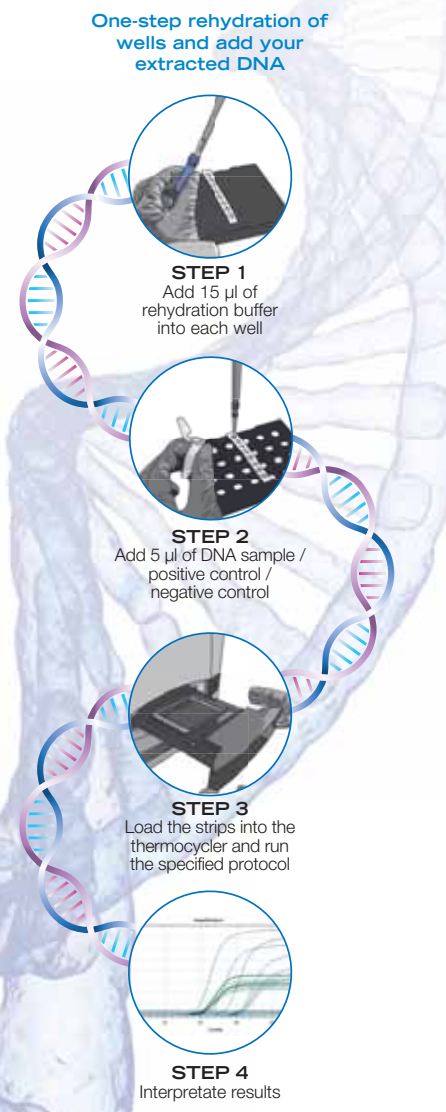
Components

Reagent/Material	Description	Colour	Quantity
<i>H. pylori</i> + Clarithromycin resistance 8-well strips	A mix of enzymes, primers-probes, buffer, dNTPs, stabilizers and Internal control in stabilized format	White	6/12 x 8-well strip
Rehydration Buffer	Solution to reconstitute the stabilized product	Blue	1 vial x 1,8 mL
<i>H. pylori</i> + Clarithromycin resistance Positive Control	Non-infectious synthetic lyophilized cDNA	Red	1 vial
Negative Control	Non template control	Violet	1 vial x 1 mL
Water RNase/DNase free	Water RNase/DNase free	White	1 vial x 1 mL
Tear-off 8-cap strips	Optical caps for sealing Wells during thermal cycling	Transparent	6/12 x 8-cap strip

Kit References

Reference	Description
VS-CLA106L	Viasure <i>H. pylori</i> + Clarithromycin resistance Real Time PCR Detection Kit 6 x 8-well strips, low profile
VS-CLA106H	Viasure <i>H. pylori</i> + Clarithromycin resistance Real Time PCR Detection Kit 6 x 8-well strips, high profile
VS-CLA112L	Viasure <i>H. pylori</i> + Clarithromycin resistance Real Time PCR Detection Kit 12 x 8-well strips, low profile
VS-CLA112H	Viasure <i>H. pylori</i> + Clarithromycin resistance Real Time PCR Detection Kit 12 x 8-well strips, high profile
VS-CLA113L	Viasure <i>H. pylori</i> + Clarithromycin resistance Real Time PCR Detection Kit 96-well plate, low profile
VS-CLA113H	Viasure <i>H. pylori</i> + Clarithromycin resistance Real Time PCR Detection Kit 96-well plate, high profile

Work Flow



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