VIASURE
by certest

IVDR CERTIFIED

"Ready & Easy-to-use" kits.
Lyophilised product

Transport and storage at room temperature.
Shelf-life: 24 months

CE marked

GASTRO INFECTION
CLA
MULTIPLEX

H. pylori + Clarithromycin resistance

- *Helicobacter pylori* (*H. pylori*) is a gram-negative microaerophilic spiral-shaped bacterium, which colonize the mucus layer of the human stomach and the upper part of small intestine.

  More than half of the world population is estimated to be infected with *H. pylori*, but most individuals are asymptomatic. *H. pylori* is involved in the pathogenesis of atrophic gastritis, gastroduodenal ulcer, gastric cancer, and gastric mucosa-associated lymphoid tissue (MALT) lymphoma.

- Clarithromycin is a bacteriostatic antibiotic mostly used to treat *H. pylori* infection. 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, so that, treatment results ineffective and infection becomes chronic and more dangerous.

  The adoption of molecular techniques has allowed more rapid detection and identification of patients who suffer of this infection. Thus, it provides the critical information for determining quicker and more appropriate therapies.

- **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 gastric tissue biopsies. After DNA isolation, the identification of *H. pylori*, *Clarithromycin resistance* and/or *Clarithromycin* wild-type sequence in the 23S rRNA is performed by the amplification of a conserved region of ureB and 23S rRNA genes respectively, using specific primers and a fluorescent-labeled probe.

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H. pylori + Clarithromycin resistance

VIASURE *H. pylori* + *Clarithromycin resistance* Real Time PCR Detection Kit contains in each well all the components necessary for real time PCR assay (specific primers/probes, dNTPS, buffer, polymerase) in an stabilized format, as well as an internal control to discard the inhibition of the polymerase activity.

Point mutations in the 23S rRNA gene of *H. pylori* (A2142G and A2143G), which confer resistance to Clarithromycin are amplified and detected in FAM channel, *H. pylori* DNA targets are amplified and detected in ROX channel, Clarithromycin wild-type sequence in the 23S rRNA gene DNA targets are amplified and detected in HEX, VIC or JOE channel and the internal control (IC) in Cy5 channel.

Analytical sensitivity

VIASURE *H. pylori* + *Clarithromycin* resistance Real Time PCR Detection Kit has a detection limit of ≥10 DNA copies per reaction for point mutation A2142G and A2143G in the 23S rRNA gene, for *Clarithromycin* wild-type sequence in the 23S rRNA gene, and for *H. pylori* with a positive rate of 95%.

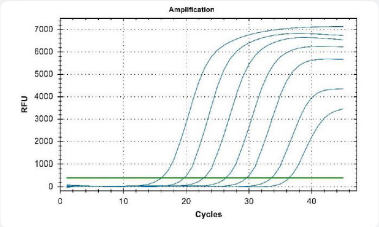

Figure 1.
Dilution series of *Clarithromycin resistance* (10^7-10^1 copies/rxn) template run on the Bio-Rad CFX96™ Real-Time PCR System (channel FAM).

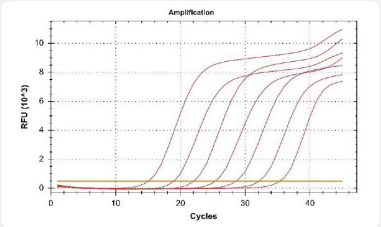

Figure 2.
Dilution series of *H.pylori* (10^7-10^1 copies/rxn) template run on the Bio-Rad CFX96TM Real-Time PCR System (channel ROX)

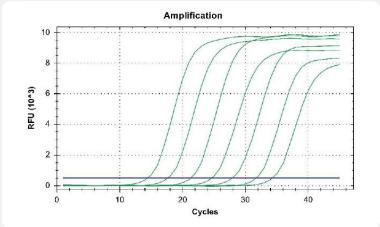

Figure 3.
Dilution series of *Clarithromycin* wild-type sequence (10^7-10^1 copies/rxn) template run on the Bio-Rad CFX96™ Real-Time PCR System (channel HEX).

For more information and use procedure, read the instructions for use included in this product.

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