

CE-IVD Marked

World's 1st technology

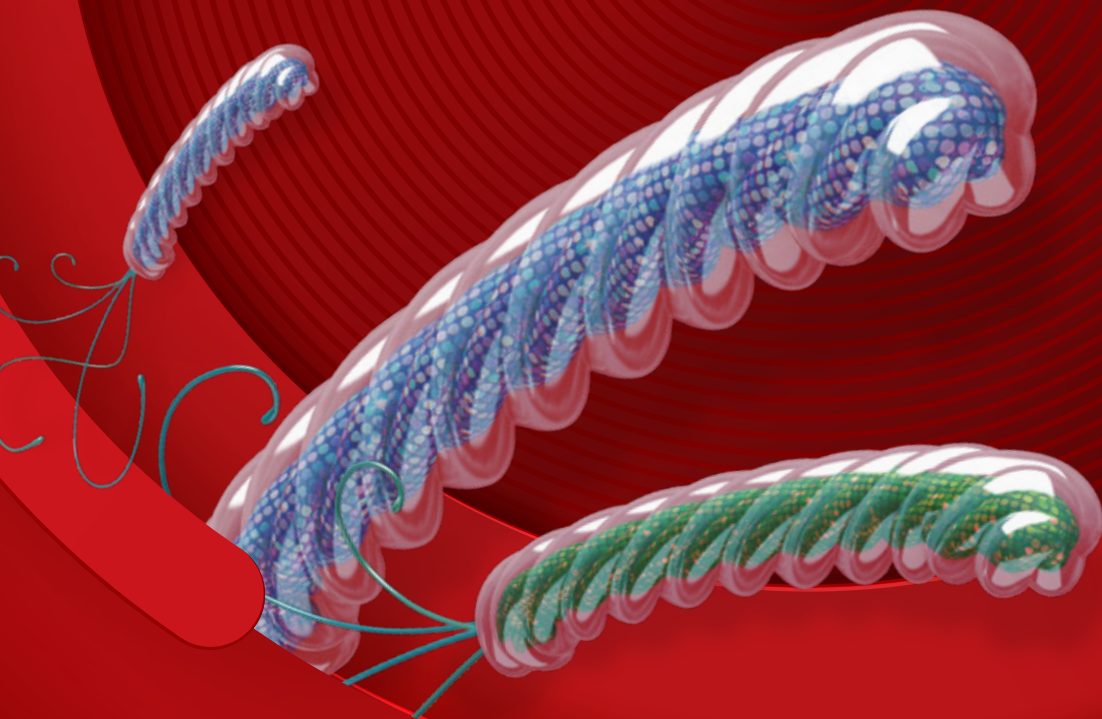
Individual Ct value of multiple analytes in a single channel

all Allplex™

H. pylori & ClariR Assay

Simultaneous detection and identification of
Helicobacter pylori and 3 major mutations causing
clarithromycin-resistance using multiplex real-time PCR

H. pylori / A2142G / A2143G / A2142C



HIGH SENSITIVITY & SPECIFICITY

Multiplex real-time PCR with high sensitivity and specificity by
utilization of DPO™ and TOCE™ technologies

 **Seegene**



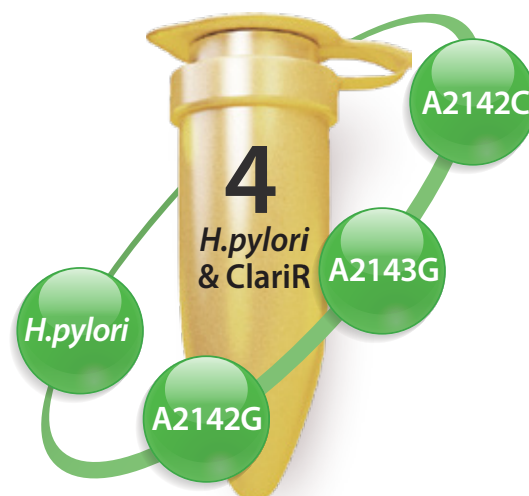
Allplex™ H.pylori & ClariR Assay

Simultaneous detection and identification of *Helicobacter pylori* and 3 major mutations causing clarithromycin-resistance using multiplex real-time PCR

The prevalence of *Helicobacter pylori* (*H. pylori*) infection varies greatly among countries. In developing countries, it is over 70% while industrialized nations show prevalent from 20% to 50%¹⁾. Infection with *H. pylori* is considered a major cause of chronic gastritis and peptic ulcer disease²⁾ and it is correlated with stomach cancer.

The "Triple Therapy" is first-line eradication therapy, which consists of a combination of Amoxicillin, Clarithromycin and a proton pump inhibitor³⁾. However, clarithromycin resistance is increasing worldwide, and it has been considered as the main factor reducing about 30% of efficacy of *H. pylori* therapy⁴⁾.

Allplex™ H. pylori & ClariR Assay is a multiplex real-time PCR assay that detects and identifies *H. pylori* and the most frequent point mutations (A2142G, A2143G and A2142C) responsible for clarithromycin resistance within the *H. pylori* 23S rRNA gene.



Key features

- Simultaneous detection and identification of *H. pylori* and major mutations (A2142G, A2143G, A2142C) responsible for clarithromycin resistance
- Cost-effective diagnostic test :
Allows detection of *H.pylori* infection and clarithromycin resistance in a single test
- Typing for each mutation type
- Only 4 hours from extraction to the final results
- Automated data interpretation with Seegene Viewer

Specimens

- Gastric biopsy specimen*
- Stool

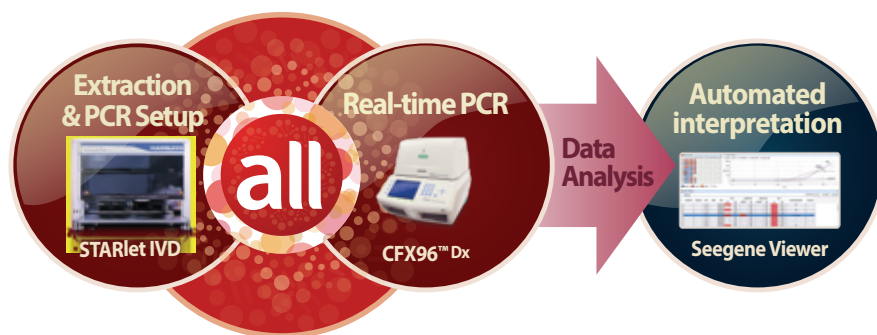
* Automated PCR setup only

Compatible instrumentation (CE-IVD Marked)

- Automated Extraction & PCR Setup :
Seegene NIMBUS, Seegene STARlet
- Automated Extraction :
NucliSENS® easyMAG® (BioMérieux)
- Real-time PCR :
CFX96™ Dx

Analytes

- *H. pylori*
- A2142G
- A2143G
- A2142C
- Internal Control (IC)



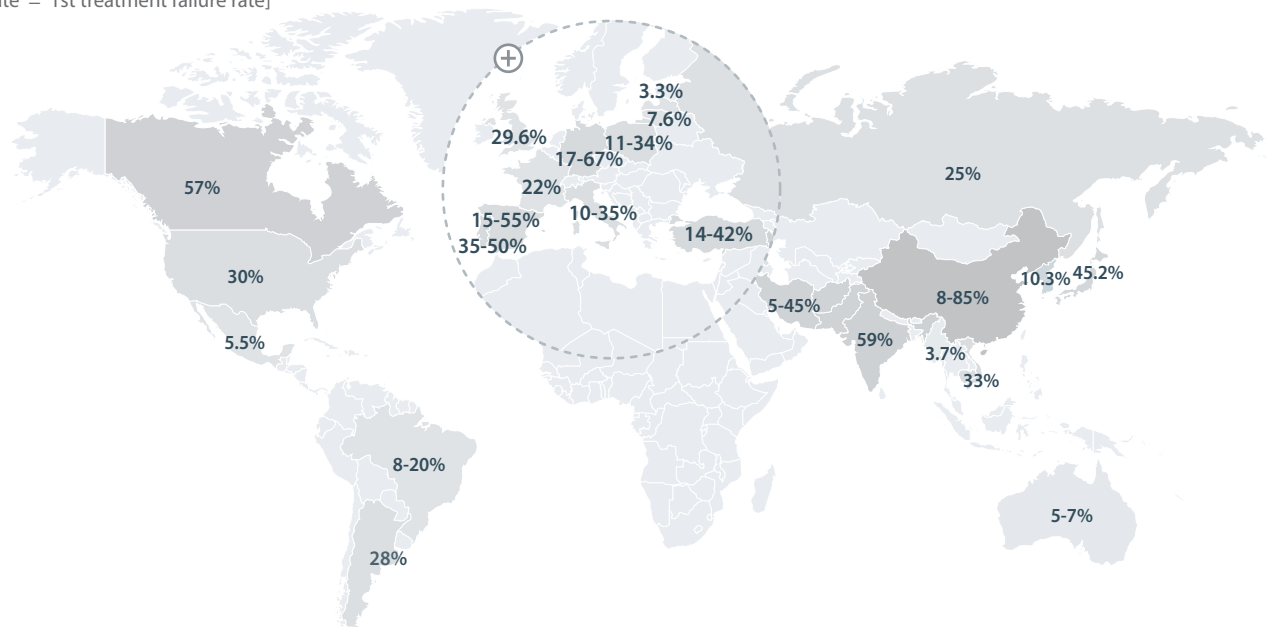
Powerful automated platform for a complete test process

- User-friendly automation system
- Automatic data interpretation software optimized for multiplex assays
- Interlocked with LIS
- Multi-Ct values in a single channel

Why should we change to MDx for *H. pylori* testing?

1. Prevalence of Clarithromycin Resistance Worldwide⁵⁾

[ClAr rate = 1st treatment failure rate]



2. Characteristics of *H. pylori* diagnosis methods

Method	Sensitivity	Specificity	Price	Convenience & time	Drug resistance check
Stool Ag test (SAT)	😊	😊	😊	😊	😞
Urea breath test	😊	😊	😊	😊	😞
Urease test	😊	😊	😊	😊	😞
Histology (staining)	😊	😊	😊	😐	😞
Culture (<i>H. pylori</i> & DR)	😞	😊	😊	😞	😊
MDx (<i>H. pylori</i> & DR)	😊	😊	😊	😊	😊

Result of Allplex™ *H. pylori* & ClariR Assay



Seegene Viewer

Quick and easy data analysis & interpretation

- Interface specialized for multiplex testing
- Interlocked with LIS
- Patient information input via barcode scanning system or LIS a
- Printable in various formats
- Downloadable results in a CSV file



H. pylori & ClariR Assay

Key features

- Simultaneous detection and identification of H. pylori and major mutations (A2142G, A2143G, A2142C) responsible for clarithromycin resistance
- Cost-effective diagnostic test :
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Ordering Information

Not Available for Sale in the United States

Category	Product	Package Volume	Cat. No.
Allplex™	H. Pylori & ClariR Assay	50 rxns	HC10199Y
		100 rxns*	HC10200X

* For use with NIMBUS IVD and STARlet IVD only

Instrument	Type	Cat. No.
CFX96™ Dx	Real-time PCR _ Optical Reaction Module	1845097-IVD
	Real-time PCR _ Thermal Cycler	1841000-IVD
Seegene NIMBUS	Automated extraction & PCR Setup	65415-03
Seegene STARlet	Automated extraction & PCR Setup	67930-03
STARMag 96 X 4 Universal Cartridge kit	Nucleic acids extraction reagent	744300.4.UC384



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