World's 1st | One-Channel, Multi-C_t Real-time PCR Assay

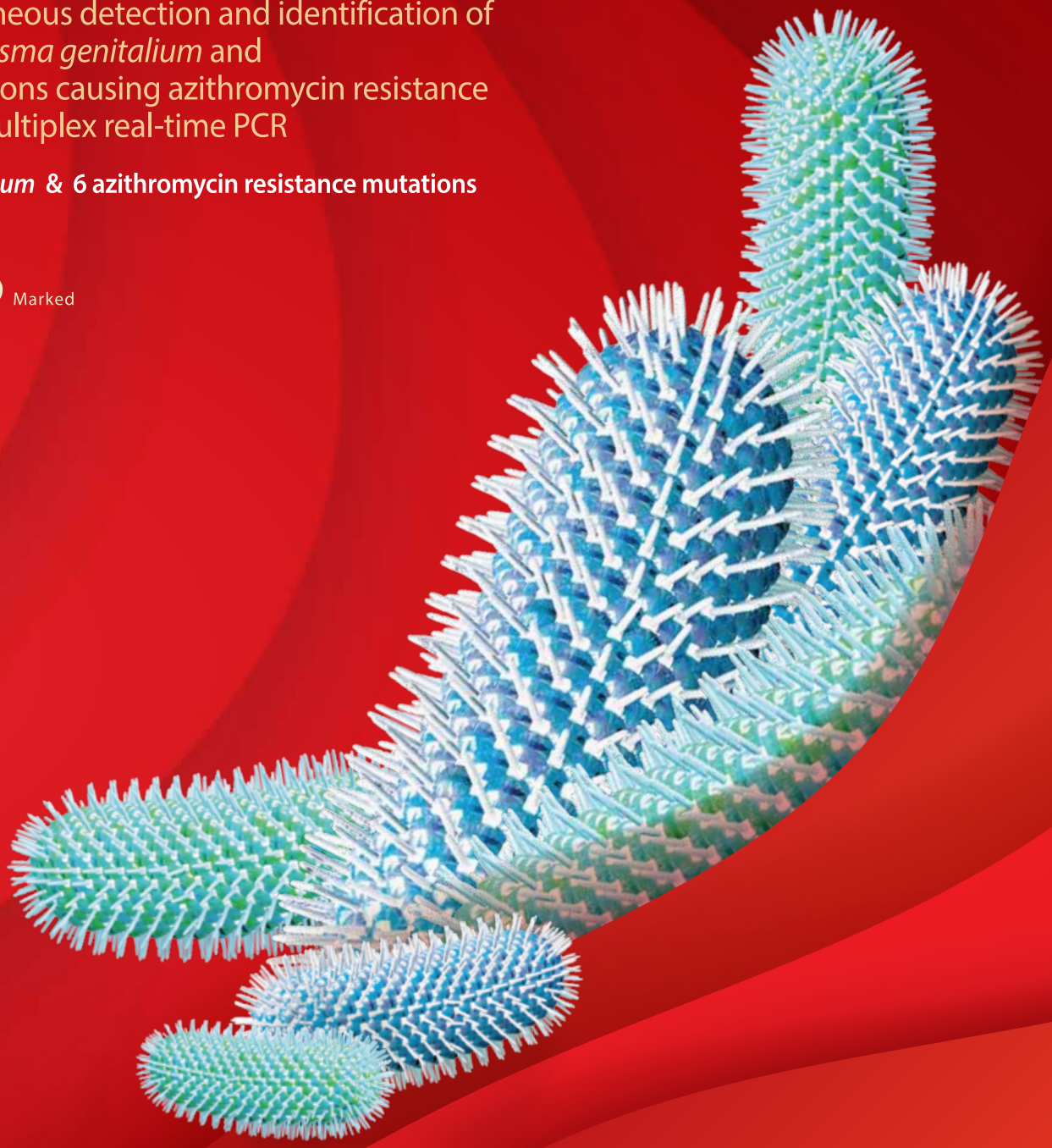
Allplex™

MG & AziR Assay

Simultaneous detection and identification of *Mycoplasma genitalium* and 6 mutations causing azithromycin resistance using multiplex real-time PCR

M. genitalium **& 6 azithromycin resistance mutations**

CE-IVD Marked



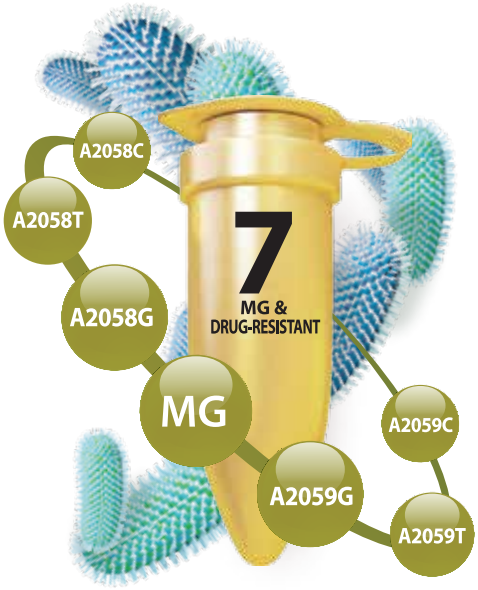
Seegene

REAL TIME | CE-IVD Marked

Allplex™ MG & AziR Assay

Simultaneous detection and identification of *Mycoplasma genitalium* and 6 mutations causing azithromycin resistance using multiplex real-time PCR

Mycoplasma genitalium (MG) is an emerging causative of sexually transmitted infections both in men and women, associated with nongonococcal uretritis and cervicitis. However, treatment of MG is complicated due to antibiotic resistance to the standard treatment, azithromycin.



Key features

- Simultaneous detection and identification of MG and 6 mutations responsible for azithromycin resistance
- Cost-effective diagnostic test
  : Allows to check MG infection and azithromycin resistance in a single test
- Informative data with typing for each mutations
- Short TAT (3.5 hours) from extraction to the final results
- Automatic data interpretation by Seegene Viewer

Analytes

- *M. genitalium*
- A2058G
- A2058T
- A2058C
- A2059G
- A2059T
- A2059C
- Internal control

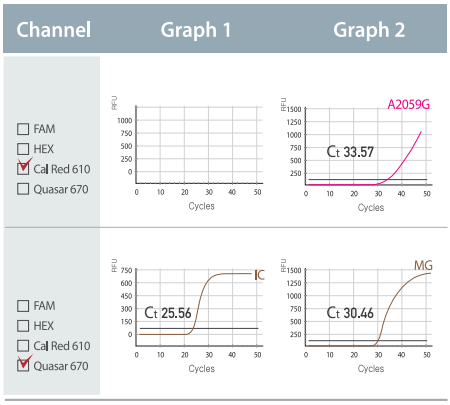
Specimens

- Genital swab
- Urine
- Liquid based cytology
  (e.g., ThinPrep® and Surepath™)

Compatible instrumentation (CE-IVD Marked)

- **Automated Extraction & PCR Setup**
  NIMBUS IVD (Hamilton)
  STARlet IVD (Hamilton)
- **Automated Extraction**
  NucliSENS® easyMAG® (BioMérieux)
- **Real-time PCR**
  CFX96™ (Bio-Rad)

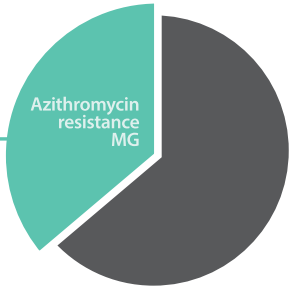
Result of Allplex™ MG & AziR Assay



The result represents detection of MG with A2059G in Quasar670 and Cal Red 610 channels with C_t values of 30.46 (Graph 2) and 33.57 (Graph 2), respectively. Allplex™ MG & AziR Assay is able to provide the information of MG and mutations causing azithromycin resistance by analyzing individual C_t value using Seegene Viewer.

Increasing drug resistance in macrolide group, increasing demands for diagnosing drug resistance MG

Approximately **40%** of the *M. genitalium* strains are resistant to azithromycin.[1]



Azithromycin has been recommended for treatment of MG but unfortunately, certain MG pathogens have become resistant to the primary azithromycin treatment.[1][2] Therefore, efficiency of first-line therapy against this pathogen is declining, and consequently, the prevalence of this pathogen in the general population is increasing insidiously.[2]

An emerging sexually transmitted infection

MG is detected in only 1% to 3.3% of men and women in the general population.

In comparison, the prevalence of MG ranges from

15~25% of men with symptomatic NGU[5]

10~30% of men presenting with NCNGU

40% of men with chronic NGU

MG can be detected in

10~30% of women with clinical cervicitis[6]

In women, among STD clinic attendees

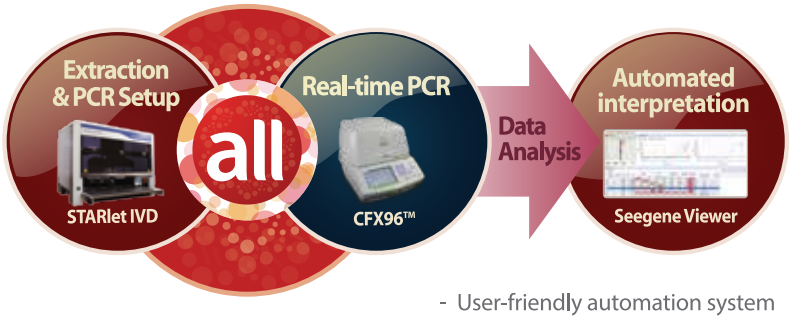
40~75% are asymptomatic[6]

Complications in women:
PID, tubal factor infertility

MG causes nongonococcal urethritis (NGU) in men and is detected in 10%–30% of men presenting with nonchlamydial nongonococcal urethritis (NCNGU) and in up to 40% of those with chronic NGU.[4] In women, MG infection is associated with significantly elevated risks of cervicitis, pelvic inflammatory disease (PID), preterm birth, infertility, and spontaneous abortion in women.[1]

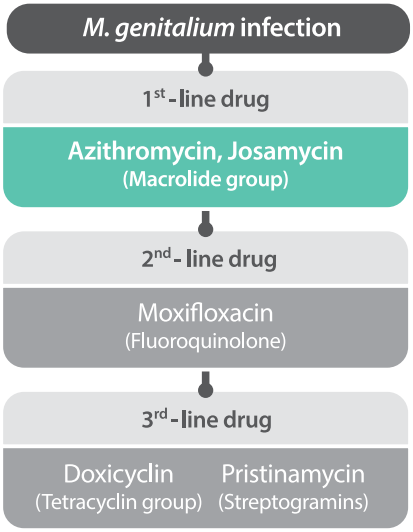
Seegene's Powerful Automation Platform for Complete Test Process

Convenient total workflow using Seegene's automation platform



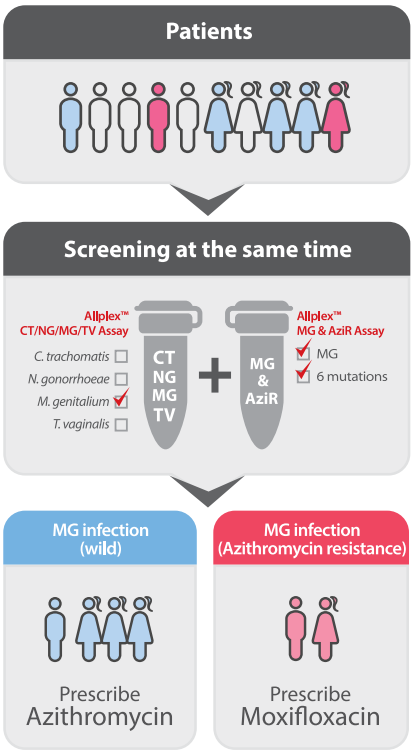
- Interlocked with LIS
- Multi-Ct values in a single channel
- User-friendly automation system
- Automatic data interpretation software optimized for multiplex assays

Treatment guidelines[3]



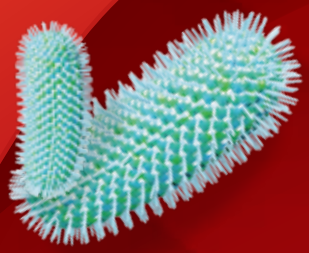
Seegene's proposal for major STI management*

Screening of 4 major STI pathogens and detection of azithromycin mutation of MG at the same time



* Based on 2016 European guideline[3]

Not Available for Sale in the United States



Key features of Allplex™ MG & AziR Assay

- Simultaneous detection and identification of MG and 6 mutations responsible for azithromycin resistance
- Cost-effective diagnostic test
  : Allows to check MG infection and azithromycin resistance in a single test
- Informative data with typing for each mutations
- Short TAT (3.5 hours) from extraction to the final results
- Automatic data interpretation by Seegene Viewer

Ordering Information

Category	Product	Package Volume	Cat. No.
Allplex™	**MG & AziR Assay**	50 rxns	SD10169Y
		100 rxns*	SD10170X

* For use with NIMBUS IVD and STARlet IVD only

Instrument	Type	Cat. No.
CFX96™	Real-time PCR_Optical Reaction Module	1845097-IVD
	Real-time PCR_Thermal Cycler	1841000-IVD
NIMBUS IVD (Microlab NIMBUS IVD)	Automated extraction & PCR Setup	65415-02
STARlet IVD (Microlab STARlet IVD)	Automated extraction & PCR Setup	173000-075
STARMag 96 X 4 Universal Cartridge kit	Nucleic acids extraction reagent	7443004.UC384

Reference

1) J. F. Braam *et. al.*, Eur J Clin Microbiol Infect Dis 2017; 36(9):1565–1567
2) Gilho Lee, Urogenit Tract Infect 2017;12(2):65-76
3) J.S.Jensen *et. al.*, 2016 European guideline on *M. genitalium* infections, JEADV, 2016
4) Andrew Lau *et. al.*, Clinical Infectious Diseases, Volume 61, Issue 9, 1 November 2015, Pages 1389–1399,
5) Elena Shipitsyna *et. al.*, PLoS One. 2017; 12(4): e0175763.
6) https://www.cdc.gov/std/tg2015/emerging.htm

Seegene

www.seegene.com

Seegene Inc.
Taewon Bldg. 91 Ogeum-ro, Songpa-gu, Seoul 05548, Republic of Korea
Tel : +82-2-2240-4000 / Fax : +82-2-2240-4040
E-mail : info@seegene.com

Seegene TECHNOLOGIES Inc.
California, USA
Tel : +1-925-448-8172
E-mail : usa@seegene.com

Seegene MIDDLE EAST
Dubai, UAE
Tel : +971-4-558-7110
E-mail : sgme@seegene.com

Seegene CANADA Inc.
Toronto, Canada
Tel : +1-800-964-5680
E-mail : canada@seegene.com

Seegene GERMANY GmbH
Düsseldorf, Germany
Tel : +49-211-9943-4260
E-mail : eu@seegene.com

MG10-EN181113B-02