ENGLISH

CE-IVD Marked

World's 1st technology

Individual Ct value of multiple analytes in a single channel

Allplex™

M. genitalium & drug-resistance Assays

Simultaneous detection and identification of
Mycoplasma genitalium and mutations responsible for
resistance of azithromycin & moxifloxacin using multiplex real-time PCR

Allplex™ MG & AziR Assay
- Azithromycin resistance

Allplex™ MG & MoxiR Assay
- Moxifloxacin resistance

Superior

HIGH SENSITIVITY & SPECIFICITY

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

Seegene

M. genitalium & drug-resistance Assays

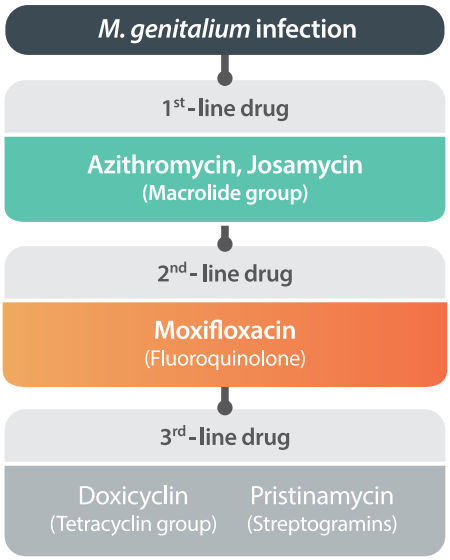
Continuing treatment of MG without diagnosis of drug resistance in MG will increase prevalence of resistance and decrease cure rate

Mycoplasma genitalium (MG) infection is a major cause of urethritis in men and is associated with cervicitis, pelvic inflammatory disease, preterm birth, and spontaneous abortion in women.

Men		Women	
15~25%	Symptomatic NGU*	10~30%	Clinical cervicitis
10~30%	NCNGU**	Among STD clinic attendees, 40~75%	are asymptomatic
40%	Chronic NGU*	Complications : PID***, tubal factor infertility	

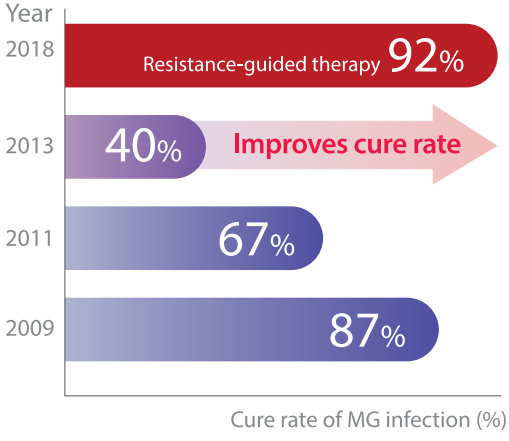
*) Non-gonococcal Urethritis, **) Non-chlamydial, ***) Pelvic inflammatory disease

Treatment guidelines[2]



Increasing macrolide and fluoroquinolone resistance in MG infection[1]

Resistance-guided therapy improves cure rate of MG infection up to 92%[3]



MG diagnostic workflow using Seegene's MG & DR Assays

Single test allows detetion and identification of MG and two drug resistances in the same day.

One time, Right result	Drug	
	1st - line	2nd - line
☑ MG	S	S
☑ MG ☑ AziR	R	S
☑ MG ☑ MoxiR	S	R
☑ MG ☑ AziR ☑ MoxiR	R	R

S) Susceptible, R) Resistant

Allplex™

REAL TIME PCR | CE-IVD Marked

MG & AziR Assay

Simultaneous detection and identification of *Mycoplasma genitalium* & 6 mutations in 23 S rRNA gene related to azithromycin resistance

Analytes

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

Allplex™

REAL TIME PCR | CE-IVD Marked

MG & MoxiR Assay

Simultaneous detection and identification of *Mycoplasma genitalium* & 6 mutations in parC gene related to moxifloxacin resistance

Analytes

- *M. genitalium*
- G248A
- G259A
- G259T
- G248T
- A247C
- G259C
- Internal control

Key features of Allplex™ MG & DR Assays

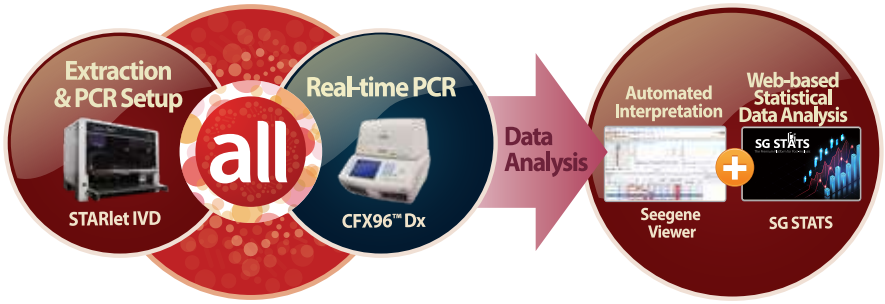
- Simultaneous detection and identification of MG and mutations responsible for resistances of azithromycin (6 mutations) and moxifloxacin (6 mutations)
- Informative data with identification of each mutation related to drug resistances
- Short TAT (3.5 hours) from extraction to the final results
- Automated data interpretation by Seegene Viewer

Specimens

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

Seegene's powerful automation platform for complete test process

Convenient total workflow using Seegene's automation platform

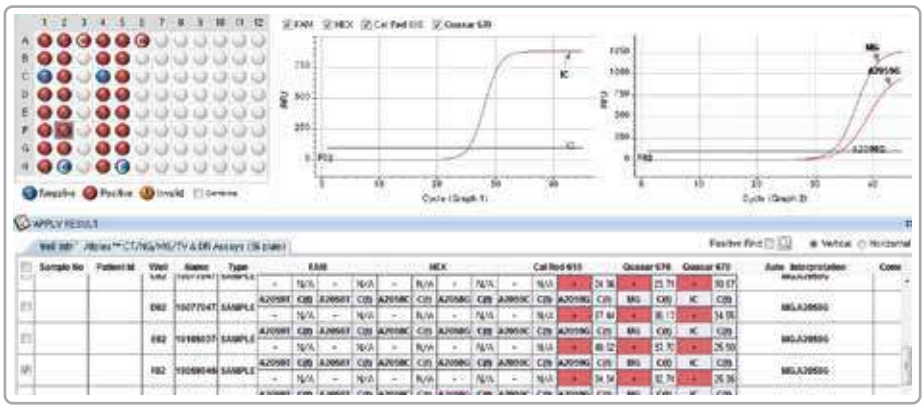


- Interlocked with LIS
- Multi-Ct values in a single channel
- User-friendly automation system
- Automated and optimized data analysis software for multiplex assays

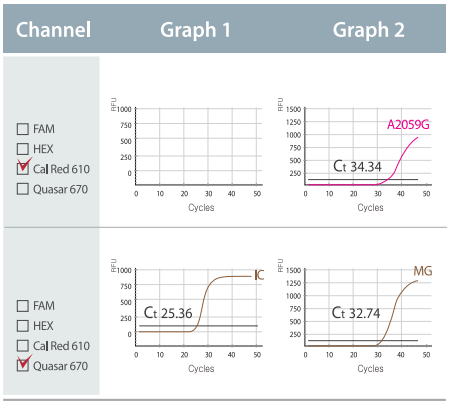
Compatible instrumentation (CE-IVD Marked)

- **Automated Extraction & PCR Setup**
  Seegene NIMBUS
  Seegene STARlet
- **Automated Extraction**
  NucliSENS® easyMAG®
  SEEPREP32™
- **Real-time PCR**
  CFX96™ Dx

Result of Allplex™ MG & DR Assays



Multiple Ct values in a single channel



The result represents detection of MG in Quasar670 with Ct values of 32.74 and A2059G in Cal Red 610 with Ct value of 34.34 (Graph 2). Allplex™ MG & AziR Assay and Allplex™ MG & MoxiR Assay are able to provide the information of MG and mutations related to azithromycin and moxifloxacin resistances by analyzing individual Ct value using Seegene Viewer.

Accurate discrimination of MG-DR mutations

Allplex™ MG & AziR and Allplex™ MG & MoxiR Assays are designed to detect and differentiate azithromycin and moxifloxacin resistance-associated mutations of MG as well as MG infection in the same time.

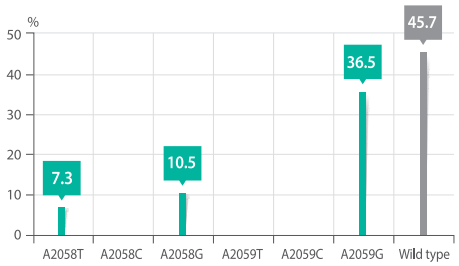
11% Multidrug-resistance mutation

43% Azithromycin resistance mutation

3% Moxifloxacin resistance mutation

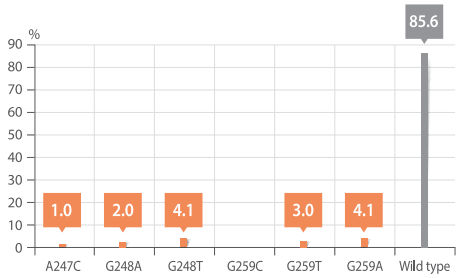
Distribution of drug-resistance mutations in MG positive samples

54% Azithromycin resistance mutation

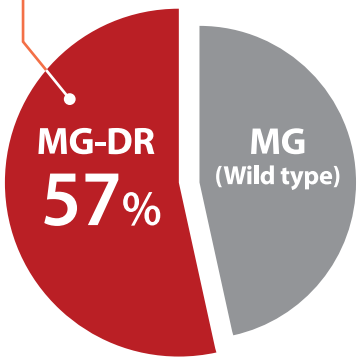


Allplex™ MG & AziR Assay

14% Moxifloxacin resistance mutation



Allplex™ MG & MoxiR Assay



Prevalence of multidrug-resistance mutations in MG infection
(azithromycin & moxifloxacin)

A total of 96 MG positive samples were tested.

- Azithromycin resistance mutations were detected in 52 (54.3%) samples; A2059G; 35 (36.5%), A2058G; 10 (10.5%), A2058T; 7 (7.3%)
- Moxifloxacin resistance mutations were detected in 14 (14.6%) samples; G248T; 4 (4.1%), G259A; 4 (4.1%), G259T; 3 (3.0%), G248A; 2 (2.0%), A247C; 1 (1.0%)
- Multidrug-resistance mutations related to AziR and MoxiR revealed in 11%.

Superior performance

Allplex™ MG & AziR Assay		
Detection	**No. of detection**	**Agreement**
MG	97 / 97	100%
Resistance markers total	53 / 97	100%
A2058T	7 / 97	100%
A2058C	0	-
A2058G	10 / 97	100%
A2059T	0	-
A2059C	0	-
A2059G	36 / 97	100%

Allplex™ MG & MoxiR Assay		
Detection	**No. of detection**	**Agreement**
MG	96 / 96*	100%
Resistance markers total	14 / 96*	100%
G259T	4 /14	100%
G259C	2 /14	100%
G259A	1 /14	100%
G248T	3 /14	100%
G248A	0	-
A247C	4 /14	100%

* 1 sample could not be amplified by sequencing

A total of 97 MG positive samples were tested.

- The results of Allplex™ MG & AziR Assay and MG & MoxiR assay showed 100% agreement with sequencing results.

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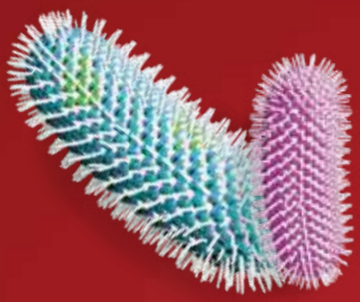

Allplex™

Allplex™ MG & DR Assays

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References

1) Emerging Infectious Disease(EID) Journal. CDC. 2018;24(2):1-228.
2) Jensen JS, et al. 2016 European guideline on Mycoplasma genitalium infections. J Eur Acad Dermatol Venereol. 2016;30(10):1650-1656.
3) Read TRH, et al. Outcomes of Resistance-guided Sequential Treatment of Mycoplasma genitalium Infections: A Prospective Evaluation. Clin Infect Dis. 2019;68(4):554-560.

Ordering Information

Category	Product	Package Volume	Cat. No.
Allplex™	**MG & AziR Assay**	50 rxns	SD10169Y
		100 rxns*	SD10170X
Allplex™	**MG & MoxiR Assay**	25 rxns*	SD10232Z
		50 rxns	SD10233Y
		100 rxns*	SD10234X

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
SEEPREP32™	Automated Extraction	SG71100
STARMag 96 X 4 Universal Cartridge Kit*	Nucleic Acids Extraction Reagent	744300.4.UC384
STARMag 96 ProPrep**	Nucleic Acids Extraction Reagent	EX00009P EX00009T

* For use with Seegene NIMBUS and Seegene STARlet, ** For use with SEEPREP32™

Not Available for Sale in the United States

Seegene

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