

Seegene's STI & Vaginitis Solutions

Extensive STI & Vaginitis product portfolio
offering multiple options to meet diverse needs

IVDR certified



Seegene's STI & Vaginitis Solutions

Seegene offers a comprehensive portfolio of STI & Vaginitis assays designed to address the evolving medical landscape, catering to the need for accurate identification of pathogens causing both sexually transmitted infections (STIs) and vaginitis. Our range of assays enables rapid screening for a wide array of STI & Vaginitis pathogens, including bacteria, fungi, viruses, and parasites, as well as detection of antimicrobial resistance genes. Regular testing is vital due to the often mild or asymptomatic nature of these infections in their early stages, which can lead to complications if left untreated. With antimicrobial resistance on the rise, simultaneous identification of infection and antimicrobial resistance genes is critical for tailored treatment strategies and improved patient outcomes.

Experience Seegene for precise testing solutions to effectively manage STIs and vaginitis.

Conduct flexible testing and discover comprehensive insights using Seegene's STI & Vaginitis diagnostic assays!

Product

Sexually transmitted infection

- Allplex™ STI Essential Assay
- Allplex™ STI Essential Assay Q (MH, UU)
- Allplex™ CT/NG/MG/TV Assay
- Allplex™ Genital ulcer Assay (Upcoming)

Vaginal infection

- Allplex™ Candidiasis Assay (Upcoming)
- Allplex™ Vaginitis Screening Assay (Upcoming)
- Allplex™ Bacterial Vaginosis *plus* Assay (Upcoming)

Antimicrobial resistance

- Allplex™ NG & DR Assay
- Allplex™ MG & AziR Assay
- Allplex™ MG & MoxiR Assay

Key features & benefits

• Test combinations tailored to meet diverse needs

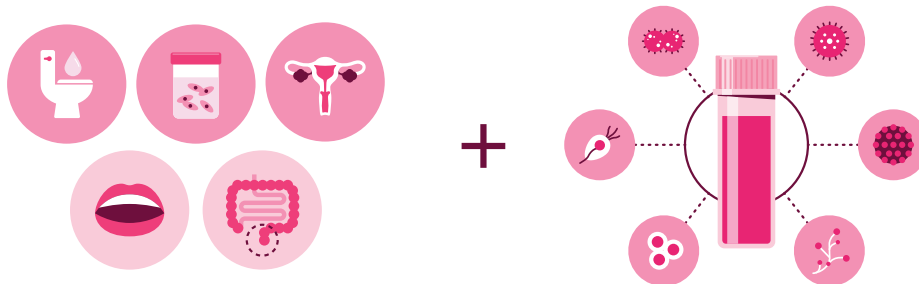
Seegene's diverse STI & Vaginitis assay portfolio can be used individually or in combination by mixing 2 to 4 panels based on needs. This enables fast and accurate screening of not only STI and vaginitis, but also AMR testing to provide comprehensive information for patient care.

Here are diverse options for customers:



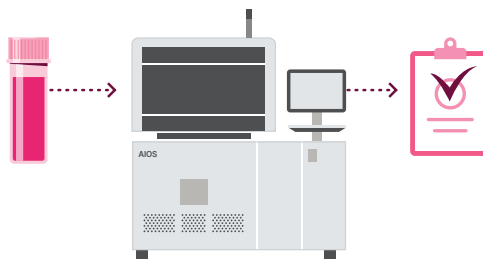
• Broad specimen options and targets

Seegene provides comprehensive coverage with a variety of specimen options and targets, detecting up to 28 targets in one test using high multiplex real-time PCR technology. It offers the advantage of testing multiple targets simultaneously without constraints or limitations.



• Versatile solutions from small to large laboratories

Seegene STARlet-AIOS™ provides a fully automated workflow from extraction to result analysis. This will maximize walk-away time while minimizing human error and contamination.



1) CDC. Sexually Transmitted Infections Treatment Guidelines, 2021. 2021; Available from <https://www.cdc.gov/std/treatment-guidelines>

2) WHO. Guidelines for the management of symptomatic sexually transmitted infections. 2021; Available from <https://www.who.int/publications/i/item/9789240024168>

3) Yassin R et al., Comparison of two commercial multiplex PCR assays for the detection sexually transmitted infections. J Infect Dev Ctries. 2022;16(2):333-338. DOI:10.3855/jidc.15279.

Allplex™ STI Essential Assay **Allplex™ STI Essential Assay Q (MH, UU)**

Comprehensive screening of 7 major pathogens with quantification information for 2 pathogens†

- Detects and identifies 7 major causative pathogens of STI simultaneously with a single test
- Applicable to anorectal and oropharyngeal specimens for CT and NG targets
- Provides quantitative results for 2 targets (MH, UU)†
- Combination test available with Seegene's other STI assays
- Provides a fully automated workflow using Seegene STARlet-AIOS™

† Applies to Allplex™ STI Essential Assay Q (MH, UU)



Analytes

C. trachomatis
N. gonorrhoeae
M. genitalium
T. vaginalis

* Quantitative

M. hominis (Q)*
U. urealyticum (Q)*
U. parvum

Endogenous internal control (IC)**

** Exogenous IC is provided for use when applying urine or anorectal swab specimen.

Specimens

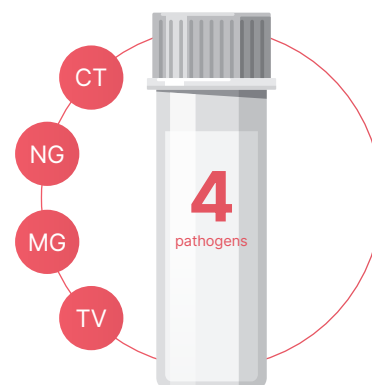
Urine
 Liquid-based cytology (ThinPrep® / SurePath™ / CellPreserv)
 Genital swab
 Oropharyngeal swab***
 Anorectal swab***

*** The detection of CT and NG are additionally validated on oropharyngeal swab and anorectal swab.

Allplex™ CT/NG/MG/TV Assay

Fast screening of 4 major causative pathogens with short PCR TAT

- Detects and identifies 4 major causative pathogens of STI simultaneously with a single test
- Applicable to anorectal and oropharyngeal specimens for CT and NG targets
- Reduces test time with fast PCR TAT of 1.5 hours
- Combination test available with Seegene's other AMR assays
- Provides a fully automated workflow using Seegene STARlet-AIOS™



Analytes

C. trachomatis
N. gonorrhoeae
M. genitalium
T. vaginalis

Endogenous internal control (IC)*

* Exogenous IC is provided for use when applying urine or anorectal swab specimen.

Specimens

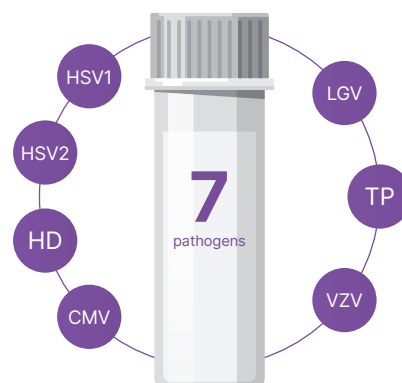
Urine
 Liquid-based cytology (ThinPrep® / SurePath™ / CellPreserv)
 Genital swab
 Oropharyngeal swab **
 Anorectal swab **

** The detection of CT and NG are additionally validated on oropharyngeal swab and anorectal swab.

Allplex™ Genital ulcer Assay (Upcoming)

Detecting 7 pathogens associated with genital ulcer

- Detects and identifies 7 causative pathogens of genital ulcer simultaneously with a single test
- Combination test available with Seegene's other STI assays
- Provides a fully automated workflow using Seegene STARlet-AIOS™



Analytes

Herpes simplex virus 1
Herpes simplex virus 2
H. ducreyi
Cytomegalovirus

Lymphogranuloma venereum
T. pallidum
Varicella-zoster virus

Specimens

Urine
Liquid-based cytology
(ThinPrep® / SurePath™)
Genital swab

Endogenous internal control (IC)*

* Exogenous IC is provided for use when applying urine specimen.

Allplex™ Candidiasis Assay (Upcoming)

Identifying 7 candida species associated with candidiasis

- Detects and identifies 7 candida species causing candidiasis simultaneously with a single test
- Detects 2 targets of candida species (*C. glabrata*, *C. krusei*) that are resistant to Azole
- Combination test available with Seegene's other STI assays
- Provides a fully automated workflow using Seegene STARlet-AIOS™



Analytes

C. albicans
C. krusei
C. glabrata
C. dubliniensis

C. parapsilosis
C. tropicalis
C. lusitaniae

Specimens

Urine
Liquid-based cytology
(ThinPrep® / SurePath™)
Genital swab

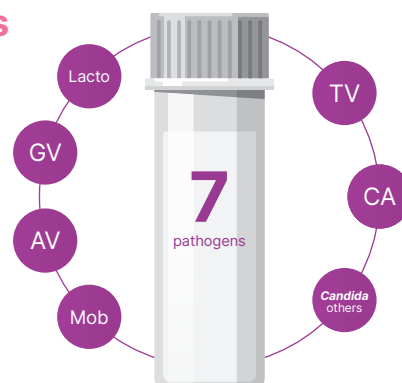
Endogenous internal control (IC)*

* Exogenous IC is provided for use when applying urine specimen.

Allplex™ Vaginitis Screening Assay (Upcoming)

Providing qualitative and quantitative information for diagnosis of 7 pathogens causing 3 major vaginitis

- Detects and identifies 7 causative pathogens of vaginitis simultaneously with a single test
- Automatically interprets the status of *bacterial vaginosis* (normal, intermediate, or bacterial vaginosis)
- Provides quantitative results for 3 vaginitis pathogens (*A. vaginae*, *Lactobacillus* spp., *G. vaginalis*)
- Provides a fully automated workflow using Seegene STARlet-AIOS™



Analytes

Lactobacillus spp. (Q)*

G. vaginalis (Q)*

A. vaginae (Q)*

Mobiluncus spp.

* Quantitative

T. vaginalis

C. albicans

Candida others

Specimens

Liquid-based cytology
(ThinPrep® / SurePath™)

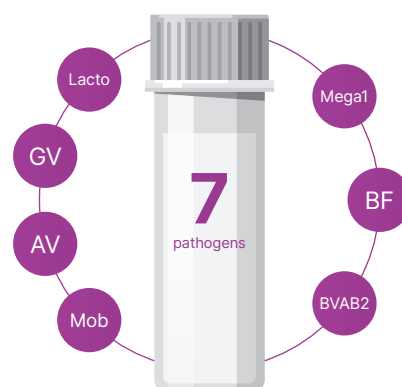
Genital swab

Endogenous internal control (IC)

Allplex™ Bacterial Vaginosis *plus* Assay (Upcoming)

Providing qualitative and quantitative information for 7 bacteria associated with vaginosis

- Detects and identifies 7 causative pathogens of bacterial vaginosis simultaneously with a single test
- Automatically interprets the status of *bacterial vaginosis* (normal, intermediate, or positive)
- Provides quantitative results for 3 bacterial vaginitis pathogens (*A. vaginae*, *Lactobacillus* spp., *G. vaginalis*)
- Combination test available with Seegene's other STI assays
- Provides a fully automated workflow using Seegene STARlet-AIOS™



Analytes

Lactobacillus spp. (Q)*

G. vaginalis (Q)*

A. vaginae (Q)*

Mobiluncus spp.

* Quantitative

Megasphaera type 1

B. fragilis

BV-associated bacteria 2

Specimens

Genital swab

Endogenous internal control (IC)

Allplex™ NG & DR Assay

Detecting *Neisseria gonorrhoeae* and 3 mutations related to azithromycin & ciprofloxacin resistance

- Detects *Neisseria gonorrhoeae* and 3 types of azithromycin & ciprofloxacin resistant mutations simultaneously with a single test
- Applicable to anorectal and oropharyngeal specimens
- Reduces test time with fast PCR TAT of 1.5 hours
- Combination test available with Seegene's other AMR assays
- Provides a fully automated workflow using Seegene STARlet-AIOS™



Analytes

N. gonorrhoeae (NG1)
N. gonorrhoeae (NG2)
A2059G
C2611T

S91F

Specimens

Urine
Liquid-based cytology
(ThinPrep® / SurePath™ / CellPreserv)
Genital swab
Oropharyngeal swab**
Anorectal swab**

Endogenous internal control (IC)*

* Exogenous IC is provided for use when applying urine or anorectal swab specimen.

** The detection of NG, A2059G, and S91F are additionally validated on oropharyngeal swab and anorectal swab.

Allplex™ MG & AziR Assay

Detecting *Mycoplasma genitalium* and 6 mutations related to azithromycin resistance

- Detects *Mycoplasma genitalium* and 6 types of azithromycin resistant mutations simultaneously with a single test
- Reduces test time with fast PCR TAT of 1.5 hours
- Combination test available with Seegene's other AMR assays
- Provides a fully automated workflow using Seegene STARlet-AIOS™

Analytes

M. genitalium
A2058G
A2058C
A2058T
A2059G
A2059C
A2059T

Endogenous internal control (IC)*

* Exogenous IC is provided for use when applying urine specimen.

Specimens

Urine
Liquid-based cytology
(ThinPrep® / SurePath™)
Genital swab



Allplex™ MG & MoxiR Assay

Detecting *Mycoplasma genitalium* and 6 mutations related to moxifloxacin resistance

- Detects *Mycoplasma genitalium* and 6 types of moxifloxacin resistant mutations simultaneously with a single test
- Reduces test time with fast PCR TAT of 1.5 hours
- Combination test available with Seegene's other AMR assays
- Provides a fully automated workflow using Seegene STARlet-AIOS™

Analytes

M. genitalium
A247C
G248A
G248T
G259C
G259T
G259A

Endogenous internal control (IC)*

* Exogenous IC is provided for use when applying urine specimen.

Specimens

Urine
Liquid-based cytology
(ThinPrep® / SurePath™)
Genital swab



Ordering information

Product	Size	Cat. No.	Instrument	Cat. No.
Allplex™ STI Essential Assay	25 rxns 50 rxns 100 rxns	SD10245Z SD9801Y SD9801X	CFX96™ Dx	1845097-IVD 1841000-IVD
Allplex™ STI Essential Assay Q (MH, UU)	25 rxns 50 rxns 100 rxns	SD10318Z SD10201Y SD10202X	Seegene NIMBUS	65415-03
Allplex™ CT/NG/MG/TV Assay	25 rxns 100 rxns	SD10317Z SD9400X	Seegene STARlet	67930-03
Allplex™ Genital ulcer Assay (Upcoming)	25 rxns 50 rxns 100 rxns	SD10177Z SD9802Y SD9802X	Seegene STARlet-AIOS™	SG72100
Allplex™ Candidiasis Assay (Upcoming)	25 rxns 100 rxns	SD10178Z SD9803X	SEEPREP32™	SG71100
Allplex™ Vaginitis Screening Assay (Upcoming)	25 rxns 100 rxns	SD10321Z SD9750X		
Allplex™ Bacterial Vaginosis <i>plus</i> Assay (Upcoming)	25 rxns 100 rxns	SD10320Z SD10159X		
Allplex™ NG & DR Assay	25 rxns 100 rxns	SD10368Z SD10367X		
Allplex™ MG & AziR Assay	25 rxns 50 rxns 100 rxns	SD10319Z SD10169Y SD10170X		
Allplex™ MG & MoxiR Assay	25 rxns 50 rxns 100 rxns	SD10232Z SD10233Y SD10234X		
			Extraction kit	Cat. No.
			STARMag 96 X 4 Universal Cartridge Kit ^{a)}	744300.4.UC384
			STARMag 96 X 4 Viral DNA/RNA 200 C Kit ^{a)}	EX00013C
			STARMag 96 ProPrep ^{b)}	EX00009P EX00009T
			STARMag 96 ProPrep C ^{b)}	EX00017P EX00017T

a) For use with Seegene NIMBUS and Seegene STARlet
b) For use with SEEPREP32™

seegene.com



Seegene HQ
Seoul, Republic of Korea
Tel: (+82) 2 2240 4000
E-mail: info@seegene.com

