

CE-IVD Marked

World's 1st technology

all Allplex™

Vaginitis Screening Assay

Convenient and accurate diagnostic solution to identify major pathogens related vaginitis using real-time PCR assay

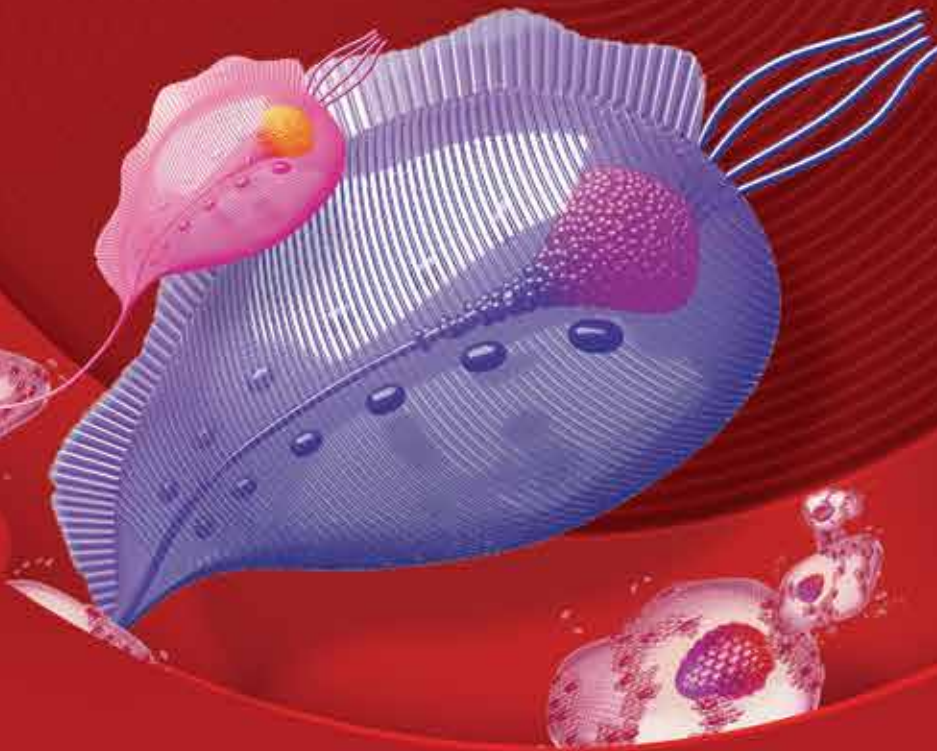
Qualitative detection

- *T. vaginalis*
- *Candida* spp.
- *C. albicans*
- *Mobiluncus* spp.

Quantitative detection

- *Lactobacillus* spp.
- *A. vaginae*
- *G. vaginalis*

Individual Ct value of multiple analyte in a single channel



HIGH SENSITIVITY & SPECIFICITY

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





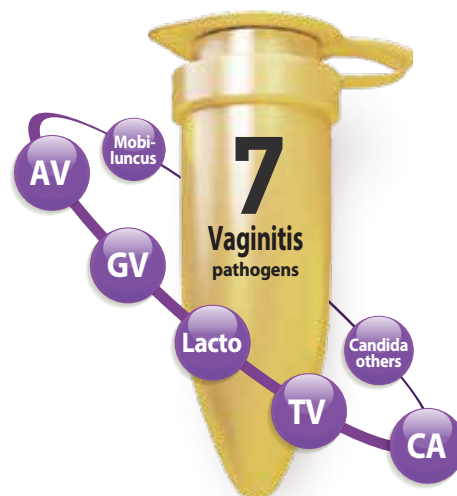
Allplex™ Vaginitis Screening Assay

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Most women have at least one episode of vaginitis during their lives. The most common causes of vaginitis are bacterial vaginosis, vulvovaginal candidiasis, and trichomoniasis. Noninfectious causes are less common and account for 5% to 10% of vaginitis cases.¹⁾ Diagnosis and treatment of each pathogens were usually recommended to reduce potential sequelae and prevent recurrent vaginitis.

Traditional diagnosis methods, such as microscopic examination, pH test of vaginal secretions and a “whiff” test, require highly trained staffs and tend to be subjective. PCR assay helps appropriate treatment through the convenient automated process and performance of highest sensitivity and specificity.

Allplex™ Vaginitis Screening Assay is a multiplex Real-time PCR assay that detects and identifies major pathogens related vaginitis simultaneously. Based on Seegene’s proprietary MuDT™ Technology, this assay reports multiple Ct value of each pathogen in a single channel. And it provides automated interpretation of BV using Seegene Viewer based on quantification information of major targets.



Key features

- Simultaneous detection of major pathogens causing vaginitis
- Providing whole process control for assay validity
- Automatic BV interpretation as Normal, Intermediate and Positive
- Automated data interpretation with Seegene Viewer

Analytes

1 tube

Bacterial Vaginosis	Vulvovaginal Candidiasis	Trichomoniasis
- <i>Lactobacillus</i> spp. ^{a)} (Q)* - <i>Gardnerella vaginalis</i> (Q) - <i>Atopobium vaginae</i> (Q) - <i>Mobiluncus</i> spp. ^{b)}	- <i>Candida albicans</i> - <i>Candida</i> others ^{c)}	- <i>Trichomonas vaginalis</i>
Whole process Internal Control		

* (Q): Quantitative

a) *L. crispatus*, *L. gasseri*, *L. jensenii* b) *M. mulieris*, *M. curtisii* c) *C. krusei*, *C. glabrata*, *C. dublinensis*, *C. parapsilosis*, *C. tropicalis*, *C. lusitanae*

Specimens

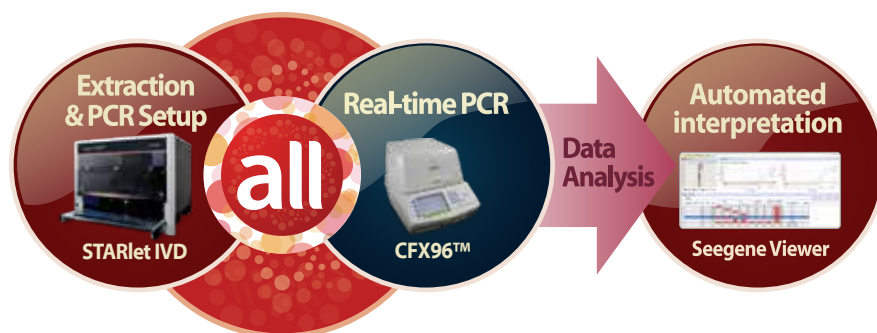
- Genital swab
- Liquid based cytology (e.g., ThinPrep® and Surepath™)

Compatible instrumentation (CE-IVD Marked)

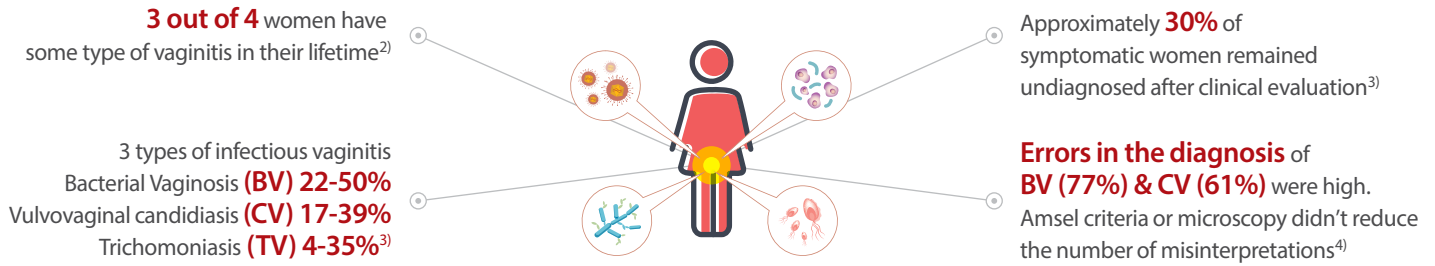
- **Automated Extraction & PCR Setup :** Seegene NIMBUS, Seegene STARlet
- **Automated Extraction :** NucliSENS® easyMAG® (BioMérieux)
- **Real-time PCR :** CFX96™ Dx

Powerful automated platform for a complete test process

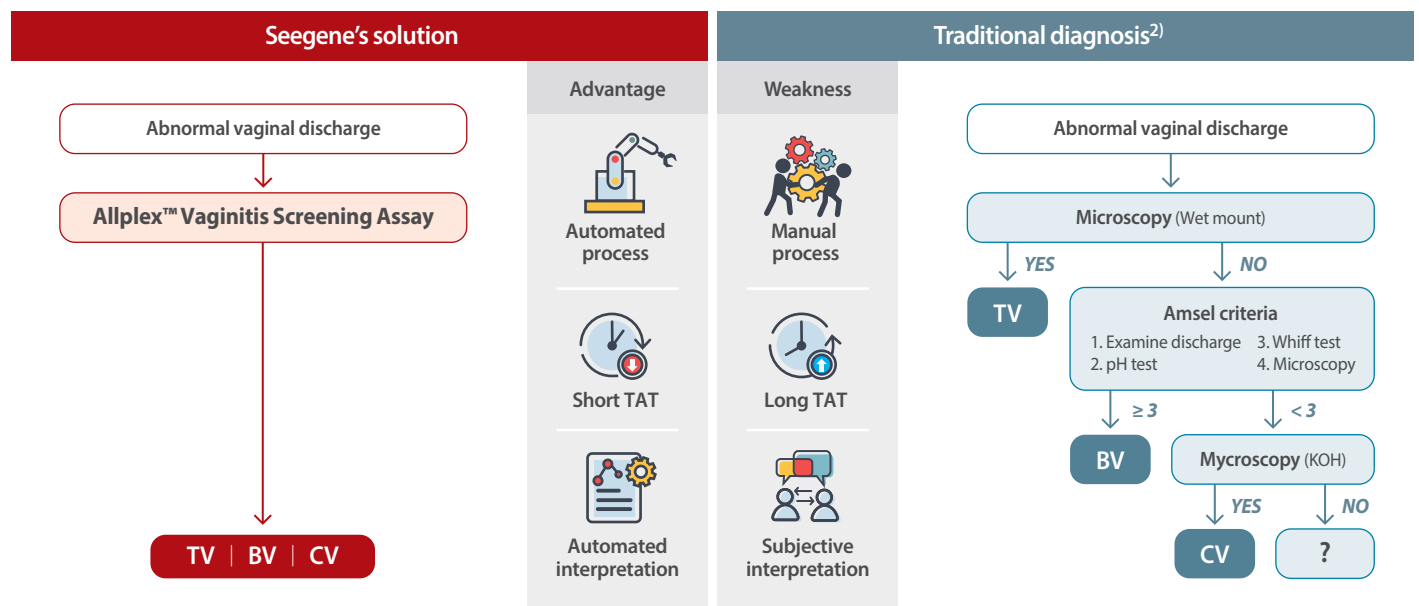
- User-friendly automation system
- Automatic data interpretation software optimized for multiplex assays
- Interlocked with LIS
- Multi-Ct values in a single channel



Management of vaginitis requires new technology



Seegene makes vaginitis diagnosis simple and accurate

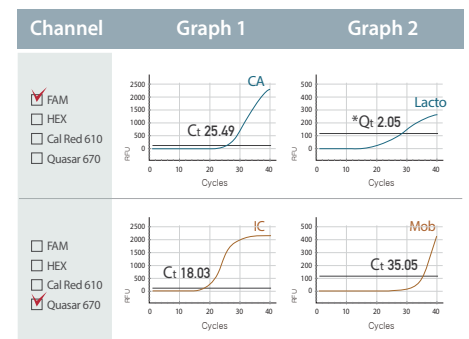


Result of Allplex™ Vaginitis Screening Assay



The result represents the co-infection of *C. albicans* (CA), *Lactobacillus* spp. (Lacto) and *Mobiluncus* spp. (Mob) in FAM (Ct values 25.49(CA) and 10^{2.05} copies/rxn(Lacto)) and Quasar 670 channel (Ct values 35.05), respectively. And this assay provides interpretation of Bacterial Vaginosis (BV) by quantitative analysis of major bacteria related vaginitis.

One channel, multi-Ct values



Example of BV Interpretation

Auto Interpretation	BV Interpretation	CA	CO	TV
GV, AV, Mob	Normal	-	-	-
Lacto, Mob	Intermediate	-	-	-
GV, AV, Mob	Bacterial Vaginosis	-	-	-
GV, TV, AV	Bacterial Vaginosis	-	-	TV
CA, GV	Bacterial Vaginosis	CA	-	-



Vaginitis Screening Assay

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Ref.

- 1) Hainer BL *et al.* Am Fam Phys. (2018) 1;97(5):321-329.
- 2) MARI E. EGAN *et al.* Am Fam Physician.(2000) 1;62(5):1095-1104.
- 3) Hainer BL *et al.* Am Fam Phys. (2011) 83(7):807-815
- 4) Andreas S *et al.* Ann Clin Microbiol Antimicrob (2006) 5: 4.

Ordering Information

Not Available for Sale in the United States

Category	Product	Package Volume	Cat. No.
Allplex™	Vaginitis Screening Assay	50 rxns	SD9750Y
		100 rxns*	SD9750X

* 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	744300.4UC384



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