

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

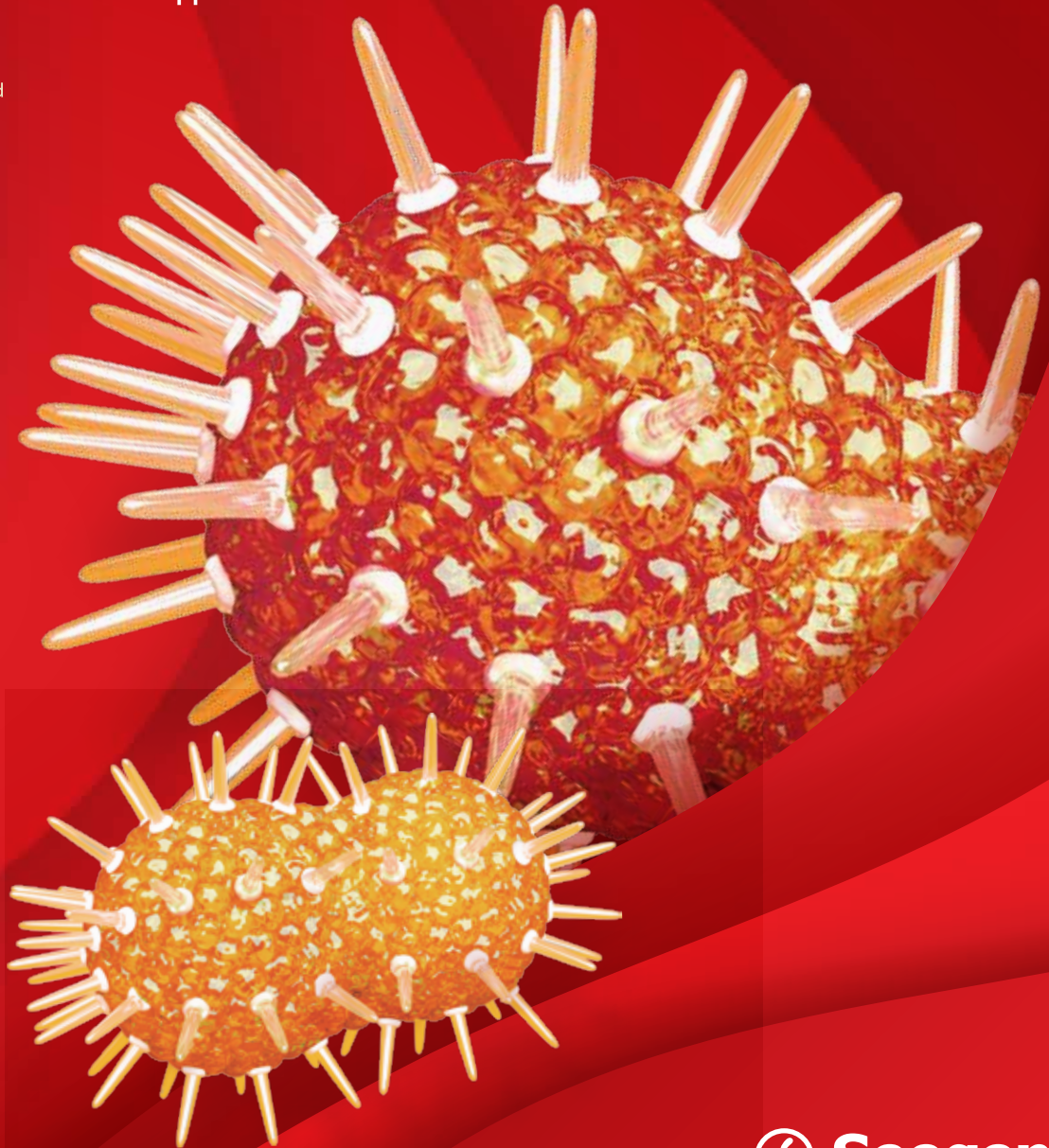
**all** Allplex™

# STI / BV Panel Assays

Comprehensive assays for the detection and identification of 28 pathogens using real-time PCR

- 4 Viruses
- 16 Bacteria
- 1 Parasite
- 7 Candida spp.

CE-IVD Marked



 **Seegene**



# STI / BV Panel Assays

Comprehensive assays for the detection and identification of 28 pathogens using real-time PCR

The burden of morbidity and mortality worldwide resulting from sexually transmitted infection (STI) compromises quality of life, as well as sexual and reproductive health and newborn and child health.<sup>1)</sup> More than 30 bacterial, viral and parasitic pathogens are transmissible sexually. Currently, STI diagnosis is various regarding to pathogens.

The multiplex real-time PCR helps early STI diagnosis by detecting multiple pathogens simultaneously in one method. Early diagnosis of STIs, including those without symptoms, is the best opportunity for effective medical treatment and support, and for preventing further transmission.

**Allplex™ STI/BV Panel Assays** is a multiplex real-time PCR assay that detects and identifies 28 STI/BV pathogens including 4 viruses, 16 bacteria, 1 parasite and 7 *Candida* spp. simultaneously. Based on Seegene's proprietary DPO™ & MuDT™ technology, this assay reports multiple Ct values of each pathogen in a single channel using real-time PCR instruments.



Ref. 1) WHO, [Global health sector strategy on sexually transmitted infections, 2016-2021] 2016

## Key Features

- Full screening for asymptomatic man or woman
- Simultaneous detection of symptom related pathogens for appropriate treatment of antifungal drugs and antibiotics
- Short TAT (4 hrs) from extraction to the final results
- Providing BV interpretation using quantitative analysis
- Informative data with individual Ct value for each analyte
- Automated data interpretation with Seegene Viewer

## Specimens

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

## Compatible Instrumentation

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

## Analytes

1 tube / 1 panel

Panel 1	Panel 2	Panel 3	Panel 4
Essential Assay	Genital ulcer	Candidiasis	Bacterial Vaginosis
<ul style="list-style-type: none"> <li>- <i>Chlamydia trachomatis</i> (CT)</li> <li>- <i>Neisseria gonorrhoeae</i> (NG)</li> <li>- <i>Mycoplasma genitalium</i> (MG)</li> <li>- <i>Mycoplasma hominis</i> (MH)</li> <li>- <i>Trichomonas vaginalis</i> (TV)</li> <li>- <i>Ureaplasma urealyticum</i> (UU)</li> <li>- <i>Ureaplasma parvum</i> (UP)</li> <li>- Internal Control (IC)</li> </ul>	<ul style="list-style-type: none"> <li>- Herpes simplex virus type 1 (HSV-1)</li> <li>- Herpes simplex virus type 2 (HSV-2)</li> <li>- Cytomegalovirus (CMV)</li> <li>- Varicella-zoster virus (VZV)</li> <li>- <i>C. trachomatis</i> serovar L (LGV)</li> <li>- <i>Treponema pallidum</i> (TP)</li> <li>- <i>Haemophilus ducreyi</i> (HD)</li> <li>- Internal Control (IC)</li> </ul>	<ul style="list-style-type: none"> <li>- <i>Candida albicans</i> (CA)</li> <li>- <i>Candida glabrata</i> (CG)</li> <li>- <i>Candida tropicalis</i> (CTp)</li> <li>- <i>Candida parapsilosis</i> (CP)</li> <li>- <i>Candida krusei</i> (CK)</li> <li>- <i>Candida lusitanae</i> (CL)</li> <li>- <i>Candida dubliniensis</i> (CD)</li> <li>- Internal Control (IC)</li> </ul>	<ul style="list-style-type: none"> <li>- <i>Gardnerella vaginalis</i> (GV)</li> <li>- <i>Atopobium vaginae</i> (AV)</li> <li>- <i>Megasphaera</i> type 1 (Mega1)</li> <li>- BV-associated bacteria 2</li> <li>- <i>Mobiluncus</i> spp.** (Mob)</li> <li>- <i>Bacteroides fragilis</i> (BF)</li> <li>- <i>Lactobacillus</i> spp.* (Lacto)</li> <li>- Internal Control (IC)</li> </ul>

\* *L. crispatus*, *L. gasseri* and *L. jensenii*, \*\* *M. mulieris* and *M. curtisii*

## Powerful Automation Platform for Complete Test Process

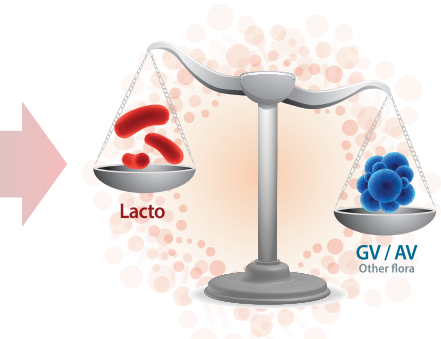


- User-friendly automation system
- Automatic data interpretation software optimized for multiplex assays
- Interlocked with LIS
- Multi-Ct values in a single channel

## Clinical Utility of Allplex™ STI/ BV Panel Assays

Clinical requirements	STI Essential Assay	Genital ulcer Assay	Candidiasis Assay	Bacterial Vaginosis Assay
STI/ BV screening for high risk	●	●	●	●
STI essential screening	●			
Genital ulcer		●		
Vaginal discharge			●	●
Cervicitis/ Urethritis	●	●		
Pelvic inflammatory disease	●			●

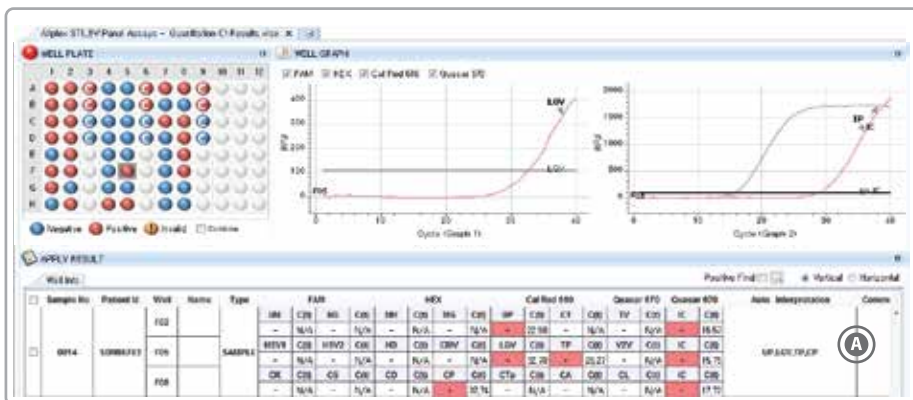
## Quantitative analysis of BV-related bacteria



Allplex™ STI/ BV Panel Assays is composed with 4 individual panels. It is useful for initial screening for sexually transmitted infections. In addition, individual panel assay can be elected for effective patient's care.

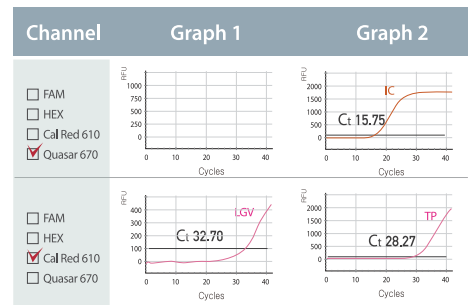
Allplex™ Bacterial Vaginosis Assay provides interpretation of Bacterial Vaginosis by quantitative analysis using standard curve

## Result of Allplex™ STI/BV Panel Assays



Seegene Viewer provides integrated results of Allplex™ STI/BV Panel Assays. The result represents co-infection of *U. parvum* (UP), *C. trachomatis* serovar L (LGV), *T. pallidum* (TP) and *C. parapsilosis* (CP) with Ct values, respectively.

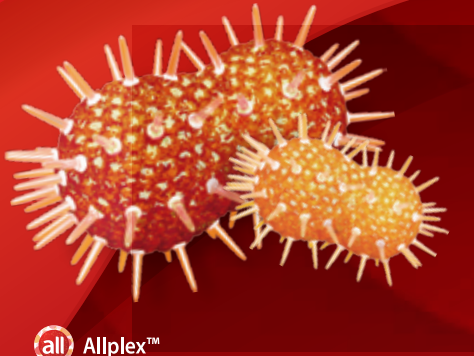
## One channel, multi-Ct values



## Example of BV interpretation

Auto Interpretation	BV Interpretation
Megal. BV. BVAS	Positive
Megal. BV. AV/Moo	Positive
Lacto	Normal
Lacto / BV	Intermediate
BV	Positive

Allplex™ Bacterial Vaginosis Assay aids diagnosis of vaginal infections by providing BV interpretation



## STI/BV Panel Assays

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### Ordering Information

Category	Product	Package Volume	Cat. No.
Allplex™	STI Essential Assay	50 rxns	SD9801Y
		100 rxns*	SD9801X
Allplex™	Genital ulcer Assay	50 rxns	SD9802Y
		100 rxns*	SD9802X
Allplex™	Candidiasis Assay	50 rxns	SD9803Y
		100 rxns*	SD9803X
Allplex™	Bacterial Vaginosis Assay	100 rxns*	SD9804X

\* 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	744300.4.UC384



[www.seegene.com](http://www.seegene.com)

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