

MuDT™ Technology



Allplex™

The Next Generation Real-time PCR Assay

- Multiple quantification and simultaneous detection of multi-targets in a single reaction
- Individual C_t values of multiple targets in a single channel
- Accurate and cost-effective disease/symptom based diagnosis for efficient management of patient care
- Multiplexed One-step Real-time RT-PCR analysis of viral RNA in a single tube
- Faster turnaround time by delivering multiple results

Not Available in U.S.A.

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)	Automated extraction & PCR Setup	65415-02
STARlet IVD (Microlab STARlet)	Automated extraction & PCR Setup	173000-075
STARMag 96 Tissue	Nucleic acids extraction reagent	744300.4.205875
STARMag 48 X 8 Tissue Cartridge Kit	Nucleic acids extraction reagent	744300.4.TC384
STARMag 96 X 4 Universal Cartridge kit	Nucleic acids extraction reagent	744300.4.UC384



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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.



Allplex™

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



all STI / BV Panel Assays

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

Allplex™ STI / BV Panel Assays is a multiplex Real-time PCR assay using the proprietary DPO™ & MuDT™ technology. The assays simultaneously detects and identifies multiple target pathogens in a single reaction, and provides multiple quantification information of targets using multiple Ct value in a single channel.

The term sexually transmitted diseases (STDs) is used to refer to a variety of clinical syndromes caused by pathogens that can be acquired and transmitted through sexual activity.¹⁾ More than 30 bacterial, viral and parasitic pathogens are transmissible sexually and constitute a group of infections called as sexually transmitted infections (STIs).

Genital ulcers have a broad differential diagnosis and may arise from infectious or noninfectious causes.²⁾ Vulvovaginal candidiasis is one of the most common infections of the female genital tract.³⁾ Most cases (80%~85%) are caused by *Candida albicans*, whereas the non-albicans species of *Candida* account for a mere 5~20% of the cases. Most of these infections with non-albicans species of *Candida* are due to *Candida glabrata* (5~10% of cases) or *Candida tropicalis* (< 5% of cases). *Candida krusei* is an unusual cause of fungal vaginitis.⁴⁾ Bacterial vaginosis (BV) is a clinical syndrome, commonly known to cause abnormal vaginal discharge in women of childbearing age, but may also be encountered in menopausal women. BV is not considered as STD, but having BV can increase your chances of getting STD. BV may also affect women who have never had sex.⁵⁾

Key Features

- Full screening for asymptomatic man or woman
- Selective panel assay for disease/symptom based or gender based diagnosis
- Simultaneous detection of symptom related pathogens (bacteria, virus and candida) for appropriate treatment of antifungal drugs and antibiotics

Specimens

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

Compatible Instrumentation (CE-IVD Marked)

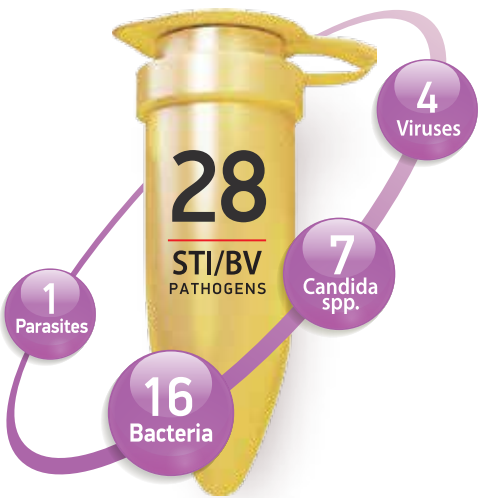
- Auto Extraction & PCR Setup : NIMBUS IVD (Hamilton), STARlet IVD (Hamilton)
- Auto Extraction : NucliSENS® easyMAG® (BioMérieux)
- Real-time PCR : CFX96™ (Bio-Rad)

Analytes

Panel 1 CE 0086	Panel 2 CE 0086	Panel 3	Panel 4
STI Essential Assay	Genital ulcer Assay	Candidiasis Assay	Bacterial Vaginosis Assay
- <i>Chlamydia trachomatis</i> (CT) - <i>Neisseria gonorrhoeae</i> (NG) - <i>Mycoplasma genitalium</i> (MG) - <i>Mycoplasma hominis</i> (MH) - <i>Trichomonas vaginalis</i> (TV) - <i>Ureaplasma urealyticum</i> (UU) - <i>Ureaplasma parvum</i> (UP) - Internal Control (IC)	- Herpes simplex virus type 1 (HSV-1) - Herpes simplex virus type 2 (HSV-2) - Varicella-zoster virus (VZV) - Cytomegalovirus (CMV) - <i>C. trachomatis</i> LGV - <i>Treponema pallidum</i> (TP) - <i>Haemophilus ducreyi</i> (HD) - Internal Control (IC)	- <i>Candida albicans</i> (CA) - <i>Candida glabrata</i> (CG) - <i>Candida tropicalis</i> (CTp) - <i>Candida parapsilosis</i> (CP) - <i>Candida krusei</i> (CK) - <i>Candida lusitanae</i> (CL) - <i>Candida dubliniensis</i> (CD) - Internal Control (IC)	- <i>Gardnerella vaginalis</i> (GV) - <i>Atopobium vaginae</i> (AV) - <i>Lactobacillus</i> spp.* (Lacto) - <i>Bacteroides fragilis</i> (BF) - <i>Megasphaera</i> type 1 (Mega1) - BV-associated bacteria 2 - <i>Mobiluncus</i> spp.** (Mob) - Internal Control (IC)

** *M. mulieris* and *M. curtisii*

*** *L. crispatus*, *L. gasseri* and *L. jensenii*



Ref.
1) CDC. [Sexually transmitted diseases treatment guidelines, 2010.] MMWR 2010;60(No. RR-12).
2) Jason S. et al., [Cutaneous Co-infected Cytomegalovirus and Herpes Simplex Virus Perigenital Ulcers in Human Immunodeficiency Virus Patients] J Clin Aesthet Dermatol. 2013;6(10):41-43
3) Saportl AM et al., [Vaginal candidiasis: etiology and sensitivity profile to antifungal agent in clinical use.] Rev Argent Microbiol. 2001;33(4):217-22
4) Singh et al., [Vaginitis Due to *Candida krusei*: Epidemiology, Clinical Aspects, and Therapy.] Clin Infect Dis. 2002;35(9): 1066-70
5) CDC. [Sexually transmitted diseases treatment guidelines, 2015.] MMWR 2015-Bacterial vaginosis

Clinical Utility of Allplex™ STI / BV Panel Assays

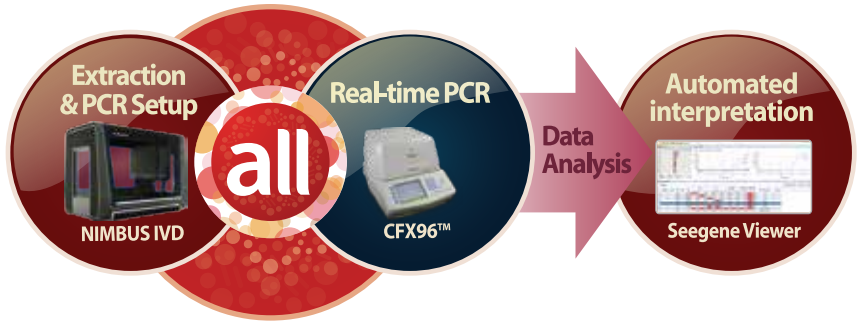
Clinical requirements	STI Essential Assay	Genital ulcer Assay	Candidiasis Assay	Bacterial Vaginosis Assay
Asymptomatic patient	STI/BV screening for woman	●	●	●
	STI screening for man	●	●	
	STI essential screening	●		
Symptomatic patient	Genital ulcer		●	
	Vaginal discharge		●	●
	Cervicitis / Urethritis	●	●	
	Pelvic inflammatory disease	●		●

Allplex™ STI / BV Panel Assays is composed with 4 individual panels.

Allplex™ STI / BV Panel Assays is useful for initial screening for sexually transmitted infections.

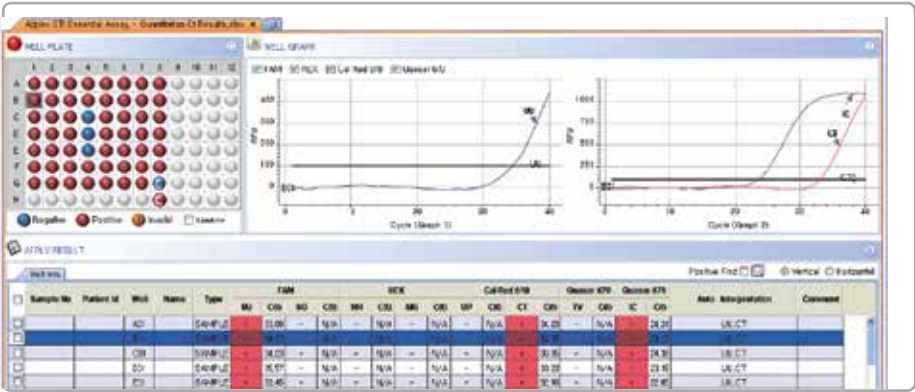
In addition, individual panel assay can be selected for effective patient's care.

Seegene's 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

Result of Allplex™ STI Essential Assay



The result represents co-infection of *U. urealyticum* (UU) and *C. trachomatis* (CT) in FAM and Cal Red 610 channel with Ct values of 34.37 (Graph 1) and 33.08 (Graph 2), respectively. Allplex™ STI Essential Assay is able to provide the information of sexually transmitted infection pathogens by analyzing individual Ct value using Seegene Viewer.

