

CE-IVD Marked

all Allplex™

CT/NG/MG/TV Assay

Efficient solution for detection of the most prevalent STI pathogens
by multiplex real-time PCR

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

World's 1st technology

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





CT/NG/MG/TV Assay

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C. trachomatis and *N. gonorrhoeae* have been managed as curable major STI pathogens. However, recently the importance of *T. vaginalis*¹⁾ and *M. genitalium*²⁾ has emerged and management has been required for the prevention of the development of complications and sequelae. The multiplex real-time PCR helps early STI diagnosis by detecting major pathogens simultaneously in one method.

Allplex™ CT/NG/MG/TV Assay is a multiplex real-time PCR assay that detects and identifies 4 STI pathogens (*C. trachomatis*, *N. gonorrhoeae*, *M. genitalium*, *T. vaginalis*) simultaneously. Based on Seegene's proprietary DPO™ & MuDT™ technology, this assay reports multiple Ct values of each pathogen in a single tube.

Ref.
1) Lori Newman et al. PLOS ONE (2015) 8;10(12):e0143304
2) CDC, Sexually transmitted diseases treatment guidelines (2015)



Key features

- Accurate results of the most prevalent STI causing pathogens in a single reaction
- Multiplexing in a short TAT (3.5 hours)
- Stable performance with dual CT and triple NG targets
- Informative data with individual Ct value for each analyte
- Providing whole process control for assay validity
- Automated data interpretation with Seegene Viewer

Analytes

- *Chlamydia trachomatis* (CT)
- *Neisseria gonorrhoeae* (NG)
- *Mycoplasma genitalium* (MG)
- *Trichomonas vaginalis* (TV)

Specimens

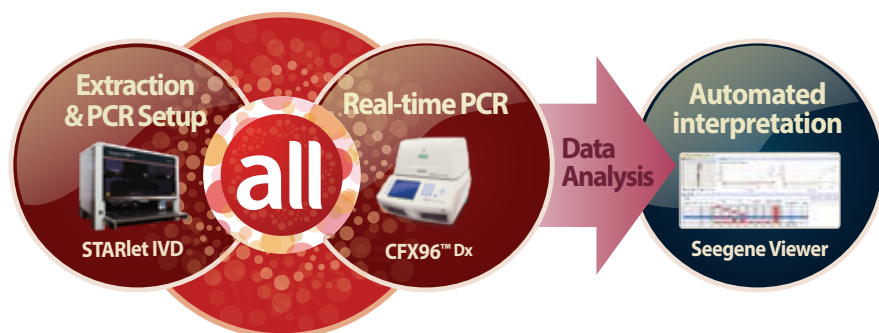
- Genital swab
- Urine
- Liquid based cytology (e.g., ThinPrep® and Surepath™)

Compatible instrumentation (CE-IVD Marked)

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

Powerful 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


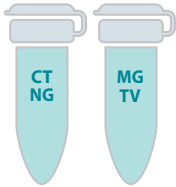
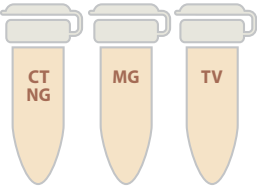


Importance of testing four STI pathogens

Patients	CT	NG	MG	TV
Asymptomatic	<ul style="list-style-type: none"> ✓ New/Multiple sexual partner ✓ Young adult women under 25y ✓ Before termination of pregnancy/IUD insertion 	<ul style="list-style-type: none"> ✓ New sexual partner 	<ul style="list-style-type: none"> ✓ Before termination of pregnancy / procedure that break the cervical barrier 	<ul style="list-style-type: none"> ✓ HIV positive
Symptomatic	<ul style="list-style-type: none"> ✓ Vaginal discharge 	<ul style="list-style-type: none"> ✓ Vaginal discharge with risk factor for STI ✓ PID ✓ Urethral discharge ✓ Cervicitis 	<ul style="list-style-type: none"> ✓ Vaginal discharge with risk factor for STI ✓ PID ✓ Urethritis(men) ✓ Cervicitis 	<ul style="list-style-type: none"> ✓ Vaginal discharge ✓ Vulvitis ✓ Vaginitis ✓ Cervicitis

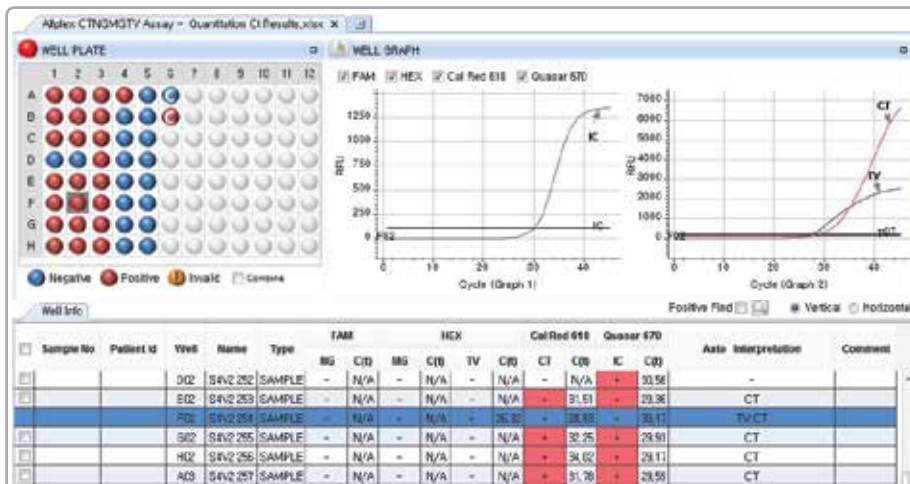
Most times STI causing pathogens are 'silent' and do not exhibit any symptoms. When exhibiting the symptoms, they are very similar and hard to distinguish a pathogen to pathogen. Because of these characteristics, it is important to identify to stop the spread of disease.

More results, Less efforts

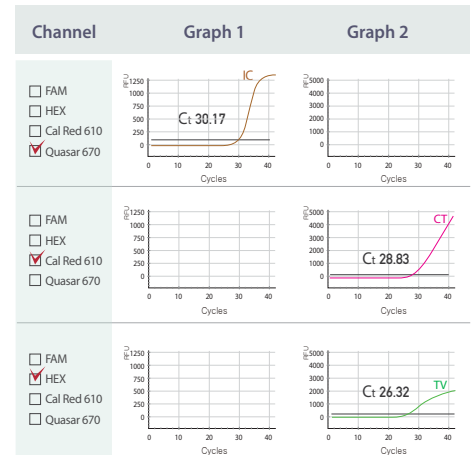
Allplex™	Product C	Product A
 <p>One test for 4 targets</p>	 <p>Two different tests for 4 targets</p>	 <p>Three different tests for 4 targets</p>

Allplex™ CT/NG/MG/TV Assay offers comprehensive, reliable, and cost-effective solutions for better patient management.

Result of Allplex™ CT/NG/MG/TV Assay



One channel, multi-Ct values



The result represents the co-infection of *C. trachomatis* (CT) and *T. vaginalis* (TV) in CalRed 610 (Ct value 28.83) and HEX channel (Ct value 26.32), respectively.



CT/NG/MG/TV Panel Assay

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- Providing whole process control for assay validity
- Automated data interpretation with Seegene Viewer

Ordering Information

Not Available for Sale in the United States

Category	Product	Package Volume	Cat. No.
Allplex™	CT/NG/MG/TV Assay	50 rxns	SD9400Y
		100 rxns*	SD9400X

* 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	65415-02
Seegene STARlet	Automated extraction & PCR Setup	173000-075
STARMag 96 X 4 Universal Cartridge kit	Nucleic acids extraction reagent	744300.4UC384



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