

Allplex™

The Next Generation Real-time PCR Assay



Allplex™

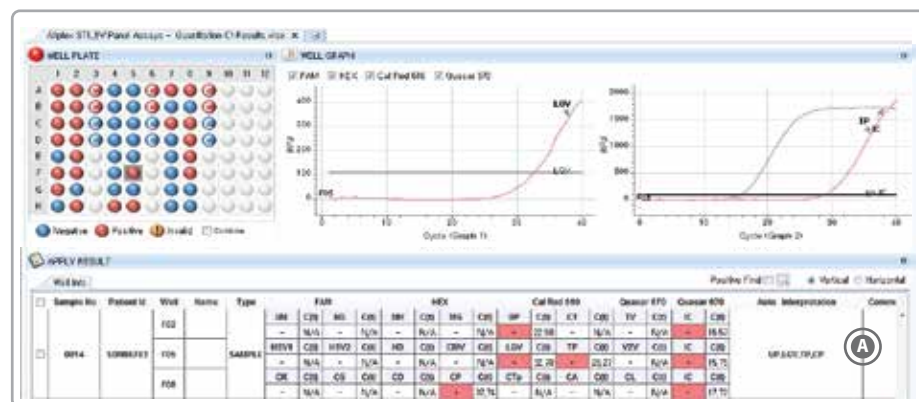
The Next Generation Real-time PCR Assay



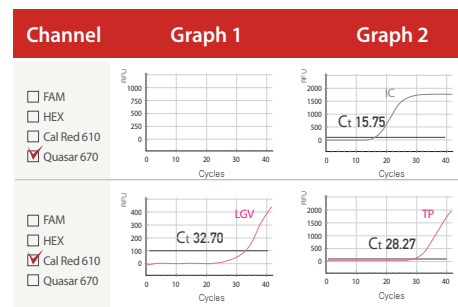
Multi-Ct values in one channel

Result of Allplex™ STI/BV Panel Assays

Powered by MuDT™ technology



Seegene Viewer provides integrated results of Allplex™ STI 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 in one patient, respectively.



A Example of BV interpretation

Auto Interpretation	BV Interpretation
Megal.GV.BV462	Bacterial Vaginosis
Megal.GV.BV462	Bacterial Vaginosis
Lacto	Normal
Lacto.GV	Intermediate
GV	Bacterial Vaginosis

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

Meningitis Panel Assays

Comprehensive assays for the detection and identification of 18 meningitis pathogens using One-step Real-time RT-PCR assay

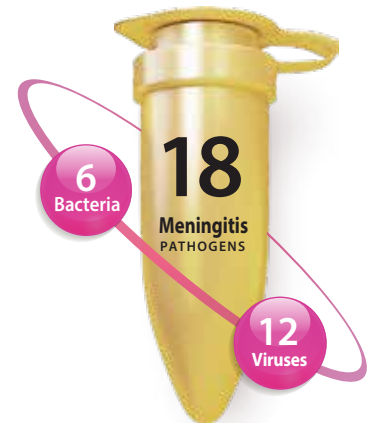
Analytes

1 tube / 1 panel

Virus (I)	Virus (II)	Bacteria
<ul style="list-style-type: none"> - Herpes simplex virus type 1 - Herpes simplex virus type 2 - Varicella-zoster virus - Epstein-barr virus - Cytomegalovirus (CMV) - Human herpesvirus 6 - Human herpesvirus 7 - Internal Control (IC) 	<ul style="list-style-type: none"> - Parvovirus B19 - Adenovirus - Mumps virus - Enterovirus - Parechovirus - Internal Control (IC) 	<ul style="list-style-type: none"> - <i>Haemophilus influenzae</i> - <i>Neisseria meningitidis</i> - <i>Streptococcus pneumoniae</i> - Group B <i>Streptococcus</i> - <i>Listeria monocytogenes</i> - <i>E.coli</i> K1 - Internal Control (IC)

Specimen

- Cerebrospinal fluid (CSF)



CE-IVD
Marked

GI-EB Screening Assay

Simultaneous identification of most prevalent causative 7 pathogens

Analytes

- *Campylobacter* spp.
- *Salmonella* spp.
- *Shigella* spp.
- *Yersinia enterocolitica*
- *Clostridium difficile* A/B
- *E. coli* O157
- STEC (*stx1/2*)
- Internal Control (IC)

Specimen

- Stool



CE-IVD
Marked

GI-Helminth(I) Assay

Simultaneous detection of 9 parasitic gastrointestinal pathogens

Analytes

- *Strongyloides* spp.
- *Necator americanus*
- *Ancylostoma* spp.
- *Ascaris* spp.
- *Trichuris trichiura*
- *Enterobius vermicularis*
- *Hymenolepis* spp.
- *Taenia* spp.
- *Enterocytozoon* spp.
- *Encephalitozoon* spp.
- Internal Control (IC)

Specimen

- Stool



CE-IVD
Marked

H. pylori & ClariR Assay

Simultaneous detection and differentiation of *H. pylori* & 3 clarithromycin resistance mutations

Analytes

- *H. pylori*
- A2142C
- A2142C
- A2143G
- Internal Control (IC)

Specimens

- Stool
- Biopsy



CE-IVD
Marked

MTB/MDR/XDR Detection

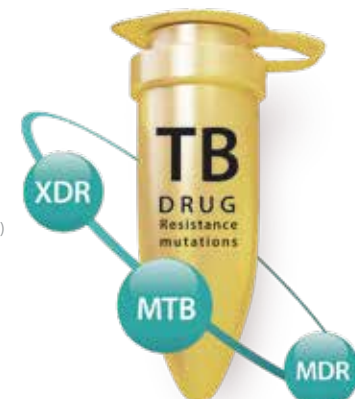
Simultaneous identification MTB and MultiDrug-resistant(MDR) and Extensively Drug resistant(XDR)

Analytes

- MTB
- MultiDrug-resistant (MDR)
 - Isoniazid-resistance (7 mutations)
 - Rifampicin-resistance (18 mutations)
- Extensively Drug resistant (XDR)
 - Fluoroquinolone-resistance (7 mutations)
 - Injectable drug-resistance (6 mutations)
- Internal Control (IC)

Specimens

- Sputum
- Cultured cell
- Bronchial washing



CE-IVD
Marked

STI / BV Panel Assays

Comprehensive assays for the detection and identification of 28 sexually transmitted infections & bacterial vaginosis pathogens

Analytes

1 tube / 1 panel

Essential Screening*	Genital ulcer	Candidiasis	Bacterial Vaginosis
<ul style="list-style-type: none"> - <i>C. trachomatis</i> - <i>N. gonorrhoeae</i> - <i>M. genitalium</i> - <i>M. hominis</i> - <i>T. vaginalis</i> - <i>U. urealyticum</i> - <i>U. parvum</i> - Internal Control (IC) 	<ul style="list-style-type: none"> - Herpes simplex virus type 1 - Herpes simplex virus type 2 - Cytomegalovirus (CMV) - Varicella-zoster virus (VZV) - LGV(<i>C. trachomatis</i> Serovar L) - <i>T. pallidum</i> - <i>H. ducreyi</i> - Internal Control (IC) 	<ul style="list-style-type: none"> - <i>C. albicans</i> - <i>C. glabrata</i> - <i>C. tropicalis</i> - <i>C. parapsilosis</i> - <i>C. krusei</i> - <i>C. lusitanae</i> - <i>C. dubliniensis</i> - Internal Control (IC) 	<ul style="list-style-type: none"> - <i>G. vaginalis</i> (Q) - <i>A. vaginae</i> (Q) - <i>Megasphaera</i> type 1 - BV-associated bacteria 2 - <i>Mobiluncus</i> spp. - <i>B. fragilis</i> - <i>Lactobacillus</i> spp.(Q) - Internal Control (IC)

(Q) Quantification * Related product: Allplex™ STI Essential Assay Q(MH,UU)

Specimens

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



CT/NG/MG/TV Assay

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

Analytes

- *C. trachomatis*
- *N. gonorrhoeae*
- *M. genitalium*
- *T. vaginalis*
- Internal Control (IC)

Specimens

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



MG & AziR Assay

Simultaneous detection of MG and 6 mutations in 23s rRNA gene related azithromycin resistance

Analytes

- *M. genitalium*
- A2058G
- A2058T
- A2058C
- A2059G
- A2059T
- A2059C
- Internal Control (IC)

Specimens

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



Vaginitis Screening Assay

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

Analytes

- *Lactobacillus* spp. (Q)
- *Gardnerella vaginalis* (Q)
- *Atopobium vaginae* (Q)
- *Mobiluncus* spp.
- *Candida albicans*
- *Candida others*
- *Trichomonas vaginalis*
- Internal Control (IC)

(Q) Quantification

Specimens

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



MG & MoxiR Assay

Simultaneous detection of MG and 6 mutations in parC gene related moxifloxacin resistance

Analytes

- *M. genitalium*
- A247C
- G248T
- G248A
- G259A
- G259C
- G259T
- Internal Control (IC)

Specimens

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



Respiratory Panel Assays

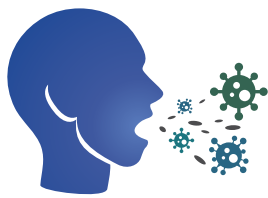
Comprehensive assays for the detection and identification of 26 pathogens using One-step Real-time RT-PCR assay

Analytes				1 tube / 1 panel
Virus (I)	Virus (II)	Virus (III)	Bacteria	
- Influenza A virus	- Adenovirus	- Bocavirus	- <i>M. pneumoniae</i>	
- Influenza B virus	- Enterovirus	- Rhinovirus	- <i>C. pneumoniae</i>	
- Respiratory syncytial virus A	- Parainfluenza virus 1	- Coronavirus NL63	- <i>L. pneumophila</i>	
- Respiratory syncytial virus B	- Parainfluenza virus 2	- Coronavirus 229E	- <i>H. influenzae</i>	
- Flu A-H1	- Parainfluenza virus 3	- Coronavirus OC43	- <i>S. pneumoniae</i>	
- Flu A-H1pdm09	- Parainfluenza virus 4	- Internal Control (IC)	- <i>B. pertussis</i>	
- Flu A-H3	- Metapneumovirus		- <i>B. parapertussis</i>	
- Internal Control (IC)	- Internal Control (IC)		- Internal Control (IC)	

Specimens	- Nasopharyngeal swab	- Bronchoalveolar lavage
	- Nasopharyngeal aspirate	- Sputum (for bacteria assay)



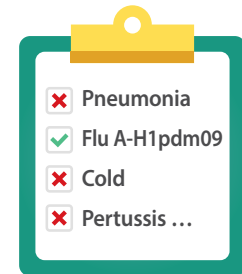
Allplex™ Respiratory Panel Assays for Symptom-Based Approach



Coughing,
wheezing patient

Allplex™ Respiratory Panel Assays

- 16 viruses
- 3 Flu A subtypes
- 7 bacteria



2019-nCoV Assay

Simultaneous screening & confirmation of COVID-19 using real-time PCR

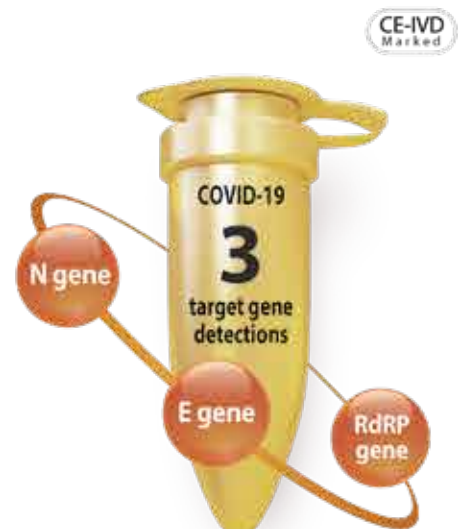
One tube, 3 target genes

Analytes	Specimens
- <i>Sarbecovirus</i> (E gene)	- Nasopharyngeal swab
- COVID-19 (RdRP gene)	- Nasopharyngeal aspirate
- COVID-19 (N gene)	- Throat swab
- Whole process control*	- Bronchoalveolar lavage
	- Sputum

Allplex™ 2019-nCoV Assay is a multiplex Real-time PCR assay that detects and identifies the novel coronavirus named as COVID-19 using three target genes** and complies with international testing protocol** for the detection of COVID-19.

* Whole process validation from extraction to PCR by whole process control

** E gene and RdRP gene recommended by Germany and German center for infection research (DZIF); N gene recommended by the US Centers for Disease Control and Prevention and the Chinese Center for Disease Control and Prevention



Gastrointestinal Panel Assays

Comprehensive assays for the detection and identification of 25 gastrointestinal pathogens using One-step Real-time RT-PCR assay

Analytes

Virus	Bacteria (I)	Bacteria (II)	Parasite
<ul style="list-style-type: none"> - Norovirus GI - Norovirus GII - Rotavirus - Adenovirus - Astrovirus - Sapovirus - Internal Control (IC) 	<ul style="list-style-type: none"> - <i>Campylobacter</i> spp. - <i>Clostridium difficile</i> toxin B - <i>Salmonella</i> spp. - <i>Shigella</i> spp. / EIEC* - <i>Vibrio</i> spp. - <i>Yersinia enterocolitica</i> - <i>Aeromonas</i> spp. - Internal Control (IC) 	<ul style="list-style-type: none"> - <i>C. difficile</i> hypervirulent - <i>E. coli</i> O157 - STEC* (<i>stx1/2</i>) - EPEC* (<i>eaeA</i>) - ETEC* (<i>lt/st</i>) - EAEC* (<i>aggR</i>) - Internal Control (IC) 	<ul style="list-style-type: none"> - <i>Giardia lamblia</i> - <i>Entamoeba histolytica</i> - <i>Cryptosporidium</i> spp. - <i>Blastocystis hominis</i> - <i>Dientamoeba fragilis</i> - <i>Cyclospora cayentanensis</i> - Internal Control (IC)

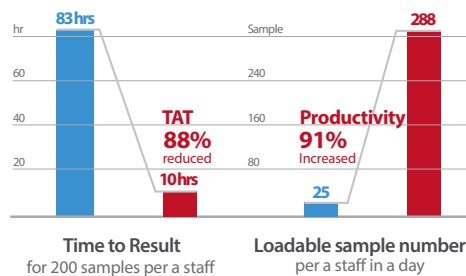
* EIEC: Enteroinvasive *E. coli*, STEC: Shiga toxin-producing *E. coli*, Enterohemorrhagic *E. coli*, EPEC: Enteropathogenic *E. coli*, ETEC: Enterotoxigenic *E. coli*, EAEC: Enterocytotoxic *E. coli*

Specimen - Stool

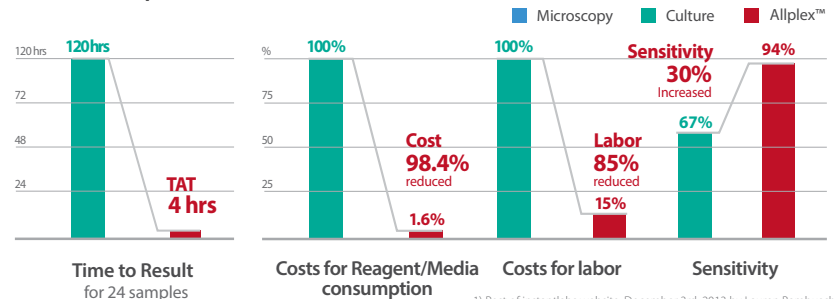


Cost DOWN !! Productivity UP !! Allplex™ Gastrointestinal Panel Assays

Microscopy vs Allplex™ for parasites¹⁾



Culture vs Allplex™ for bacteria²⁾



¹⁾ Post of instantlabs website, December 3rd, 2013 by Lauren Bambusch
²⁾ Oral presentation at 2016 ECCMID, Seegene integrated symposium

Entero-DR Assay

Simultaneous detection of antibiotic resistance genes in gram-negative and gram-positive bacteria

Analytes

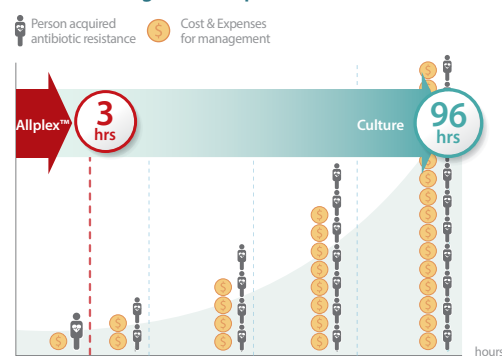
- Internal Control (IC)

CPE:	VRE:	ESBL:
- KPC	- vanA	- CTX-M
- VIM	- vanB	
- NDM		
- IMP		
- OXA-48		

Specimens

- Rectal swab - Bacterial colony

Effective management for patients



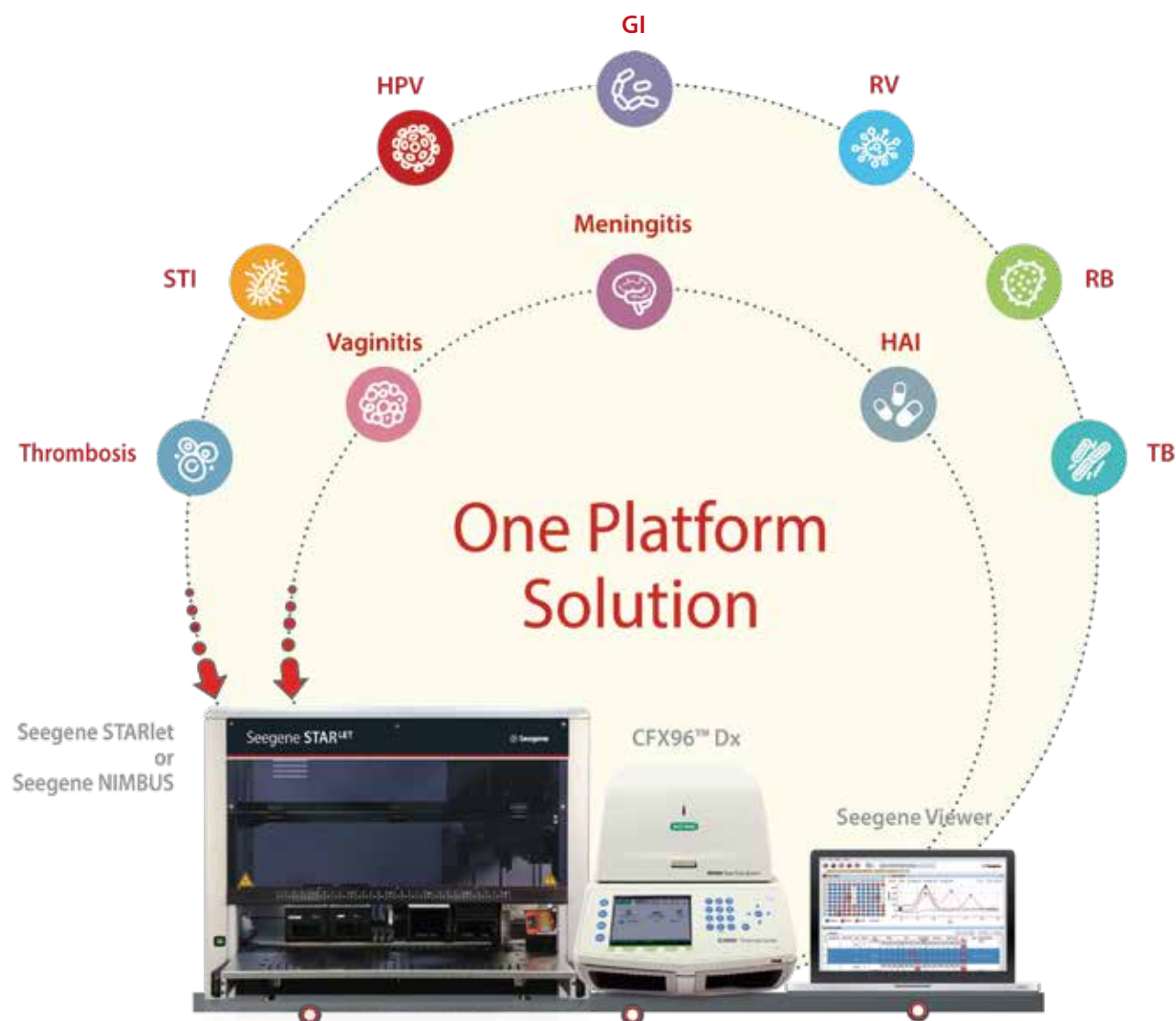
All MDx Assays in One Platform

One Platform Solution for All Molecular Diagnostics

Seegene All in One Platform allows processing various types of samples and is compatible with a comprehensive menu of molecular diagnostic assays. Seegene currently provides highly multiplex MDx assays for infectious diseases, women's health care, and personalized medicine. To help appropriate medical treatments, improve patient care and reduce the cost of healthcare, Seegene focuses on developing and expanding assays on the Seegene All in One Platform.

Broad menu of multiplex molecular diagnostic(MDx) assays in one platform

- Syndromic testing panel to provide comprehensive information
- Better patient care with excellent clinical performance
- Simplified workflow of quick and easy-to-use process



Automated Extraction & PCR Setup

- One-step process from nucleic acid extraction to PCR setup
- Minimum hands-on time & no manual pipetting
- Applicable to all types of specimens
- Mixed batch testing

Detection by Real-time PCR

- Broad MDx assays
- Superior accuracy based on DPO™, TOCE™ and MuDT™ technologies
- Multiple target detection with quantification
- Disease or symptom-based panels

Automated Data Analysis

- Optimized for multiplex MDx Assays
- Customizable report format
- Intuitive interface and convenient readout
- Interlocked with LIS

Ordering Information

Category	Product	Package Volume	Cat. No.
Women's & Sexual Health	STI Essential Assay	50 rxns	SD9801Y
		100 rxns	SD9801X
	STI Essential Assay Q(MH,UU)	50 rxns	SD10201Y
		100 rxns	SD10202X
	Genital ulcer Assay	25 rxns	SD10177Z
		50 rxns	SD9802Y
		100 rxns	SD9802X
	Candidiasis Assay	25 rxns	SD10178Z
		50 rxns	SD9803Y
		100 rxns	SD9803X
	Bacterial Vaginosis Assay	100 rxns	SD9804X
	Bacterial Vaginosis <i>plus</i> Assay	100 rxns	SD10159X
	Vaginitis Screening Assay	50 rxns	SD9750Y
		100 rxns	SD9750X
	CT/NG/MG/TV Assay	50 rxns	SD9400Y
		100 rxns	SD9400X
	MG & AziR Assay	50 rxns	SD10169Y
		100 rxns	SD10170X
Gastrointestinal Infection	GI-Virus Assay	25 rxns	SD10232Z
		50 rxns	SD10233Y
		100 rxns	SD10234X
	GI-Bacteria(I) Assay	25 rxns	GI10184Z
		50 rxns	GI9701Y
		100 rxns	GI9701X
	GI-Bacteria(II) Assay	25 rxns	GI10201Z
		50 rxns	GI9801Y
		100 rxns	GI9801X
	GI-EB Screening Assay	25 rxns	GI10183Z
		50 rxns	GI9702Y
		100 rxns	GI9702X
	GI-Parasite Assay	25 rxns	GI10196Z
		50 rxns	GI10197Y
		100 rxns	GI10198X
	GI-Helminth(I) Assay	25 rxns	GI10202Z
		50 rxns	GI9703Y
Respiratory Infection		100 rxns	GI9703X
	H. pylori infection	25 rxns	GI10189Z
		50 rxns	GI10190Y
	H. pylori & ClariR Assay	100 rxns	GI10191X
		50 rxns	HC10199Y
		100 rxns	HC10200X
	Respiratory Panel 1	25 rxns	RP10179Z
		50 rxns	RP9801Y
		100 rxns	RP9801X
	Respiratory Panel 2	25 rxns	RP10180Z
		50 rxns	RP9802Y
		100 rxns	RP9802X
	Respiratory Panel 3	25 rxns	RP10181Z
		50 rxns	RP9601Y
		100 rxns	RP9601X
Meningitis	PneumoBacter Assay	25 rxns	PB10185Z
		50 rxns	PB10175Y
		100 rxns	PB10176X
	2019-nCoV Assay	50 rxns	RP10244Y
		100 rxns	RP10243X
		25 rxns	MG10209Z
	Meningitis-V1 Assay	50 rxns	MG9700Y
		100 rxns	MG9700X
		25 rxns	MG10210Z
	Meningitis-V2 Assay	50 rxns	MG9500Y
		100 rxns	MG9500X
		25 rxns	MG10211Z
	Meningitis-B Assay	50 rxns	MG9600Y
		100 rxns	MG9600X
Hospital Acquired Infection	Entero-DR Assay	50 rxns	CR9700Y
		100 rxns	CR9700X
Tuberculosis	MTB/MDR/XDRe Detection	50 rxns	TB10173Y
		100 rxns	TB10174X

25 rxns & 100 rxns for use with Seegene NIMBUS IVD and STARlet IVD

Allplex™

The Next Generation Real-time PCR Assay

Not Available for Sale in the United States

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	744300.4.UC384

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