Seegene

Allplex™ Entero-DR Assay

Simultaneous detection and identification of
8 antibiotic resistance genes using multiplex real-time PCR

English

Allplex™ Entero-DR Assay

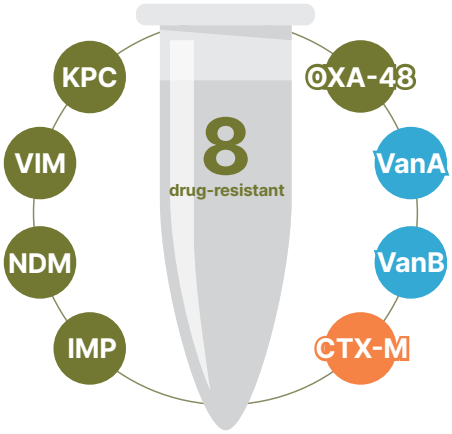
REAL TIME PCR | CE-IVD Marked

Early prevention of infection spread associated
with antimicrobial resistance that can occur in healthcare settings

Antibiotic resistant bacteria became a global concern in clinical and public health aspects due to its ability to resist the effects of antibiotics. Antibiotic resistant bacteria spread from person to person in the community (community-acquisition) or from patient to patient in hospital (hospital-acquisition). Three major bacteria that acquired antibiotic resistance include carbapenemase-producing *Enterobacteriaceae* (CPE), vancomycin-resistant *Enterococci* (VRE) and extended-spectrum beta-lactamases-producing *Enterobacteriaceae* (ESBL).

Increase in antibiotic resistance strictly limits options for treatment which results greater disability and higher mortality rates. Thus, it is significant to provide appropriate antimicrobial treatments to patients rapidly and to decrease the spread of antibiotic resistant bacteria with early diagnosis.

Allplex™ Entero-DR Assay is a multiplex Real-time PCR assay that detects and identifies 8 antibiotic resistance genes simultaneously. Based on Seegene's proprietary MuDT™ technology, this assay reports multiple C_t values of each target in a single channel without melting curve analysis.



Specimen

- Rectal swab
- Bacterial colony

Key features

- Monitoring 3 major antibiotic resistant bacteria (carbapenem, vancomycin and extended-spectrum of beta-lactam) in a single reaction
  - Identification of 3 major antibiotic resistant bacteria
  - Differentiation of each resistance gene
- Multiplexing in a short TAT
  - Detection of 8 antibiotic resistance genes within 3 hours
- Providing whole process control for assay validity
- Reporting individual C_t values for all 8 targets in a single reaction

Compatible instrumentation (CE-IVD Marked)

- **Automated extraction & PCR setup**
  Seegene STARlet-AIOS
  Seegene NIMBUS
  Seegene STARlet
- **Automated extraction**
  NucliSENS® easyMAG® (BioMérieux)
  SEEPREP32™
- **Real-time PCR**
  CFX96™ Dx

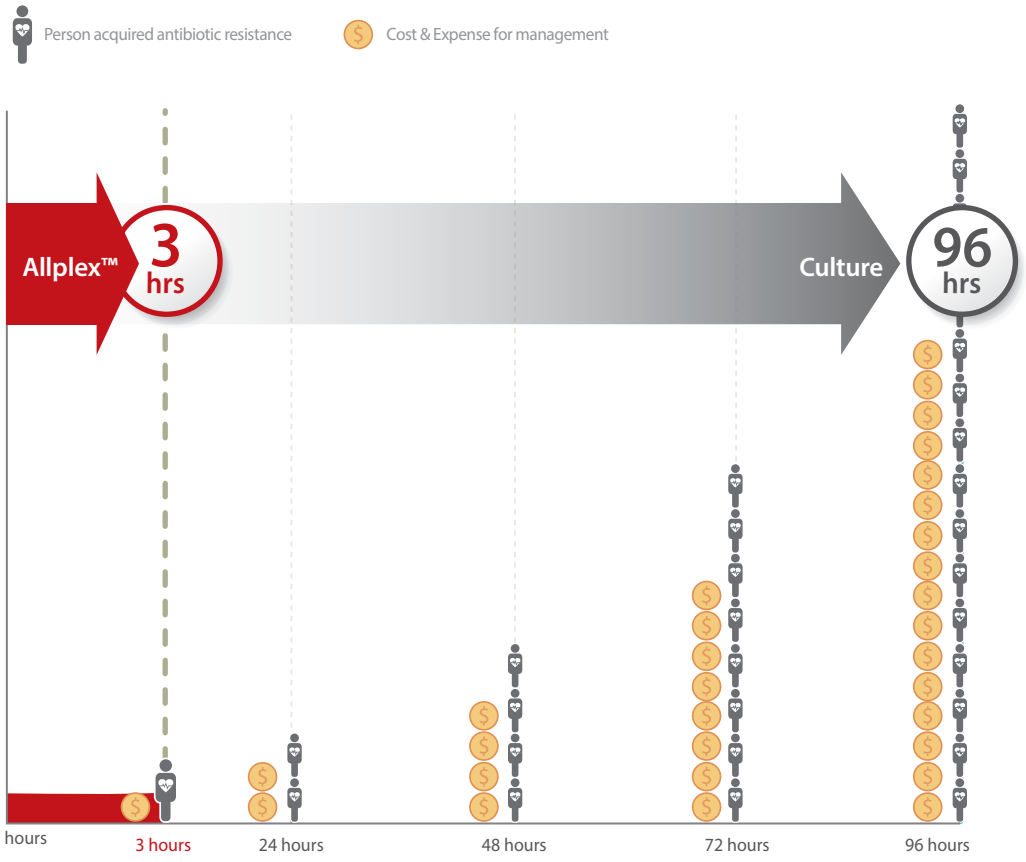
Analytes

1 tube

Carbapenemase genes (CPE)	Vancomycin-resistance genes (VRE)	Extended-spectrum beta-lactamase gene (ESBL)	
· KPC · VIM · NDM · IMP · OXA-48	· VanA · VanB	· CTX-M	· Internal Control (IC)

Why molecular test is needed?

For effective management of CPE/VRE/ESBL infections



Decrease

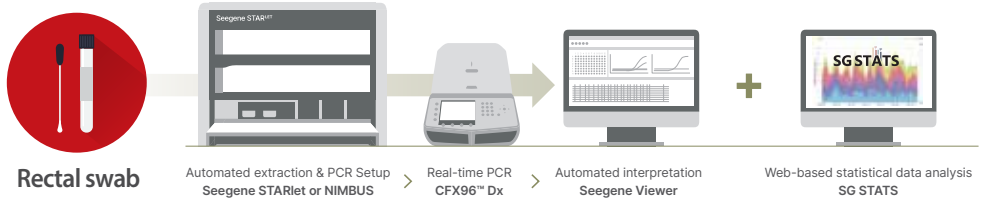
- Hygiene management costs and expenses
- Cases and outbreaks of infections
- Disability and mortality rates

Increase

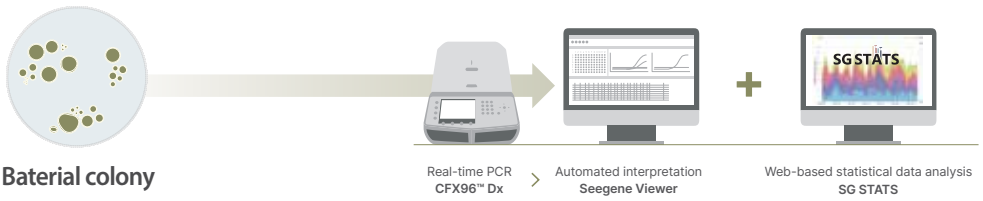
- Efficient control of patients
- Appropriate treatments
- Efficient management of healthcare-associated Infections

For proper management of patients

Short TAT allows generation of faster results and elimination of workload and labor.



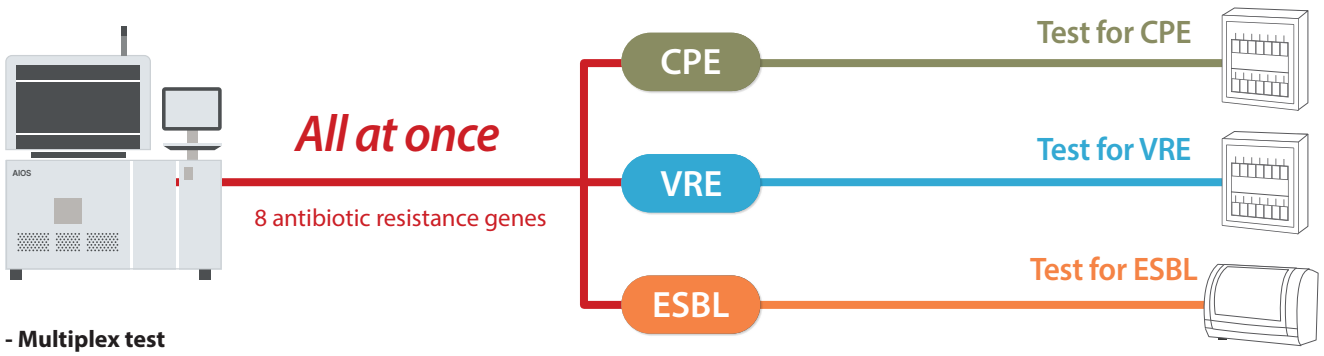
Time required for correct management and/or isolation of patients



Why Allplex™ Entero-DR Assay?

Enhances productivity

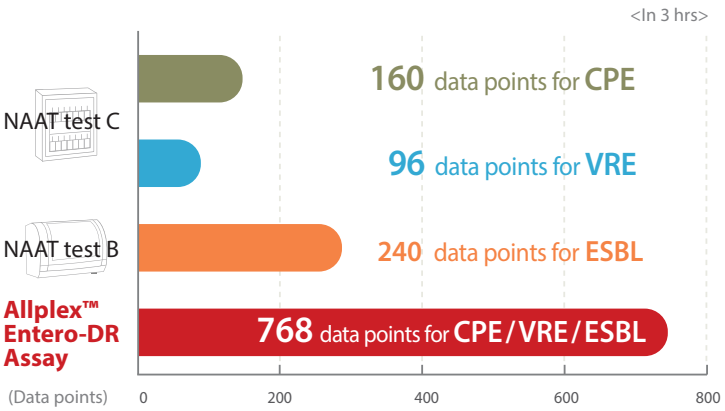
Allplex™ Entero-DR Assay	Other existing MDx assay and system



- Multiplex test
Simultaneous detection of 3 different antibiotic resistant bacteria in one test using a single sample

- Application on One Platform

- Different assays required for each antibiotic resistance gene
- Different systems required to run each assay



Provides more insights

Allplex™ Entero-DR Assay provides 768 data points (8 targets/test) for 96 samples within 3 hours for rectal swab.

Contains maximized coverage

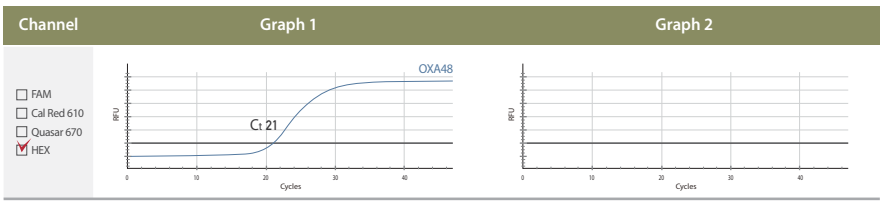
Broad spectrum of coverage in each antibiotic resistance gene allows accurate detection in 3 major antibiotic resistant bacteria.

Antibiotic resistance gene		Allplex™ Entero-DR Assay	Other existing MDx assay
CPE	KPC	25 variants	15~17 variants
	NDM	18 variants	9~10 variants
	IMP	57 variants	24 variants
	VIM	48 variants	33~37 variants
	OXA-48	20 variants	4~10 variants
VRE	VanA	●	●
	VanB	●	●
ESBL	CTX-M	5 variants	3 variants

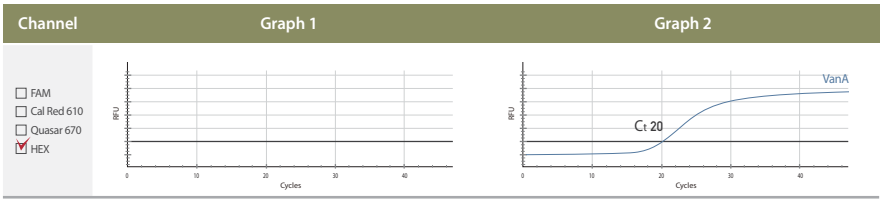
Example of Allplex™ Entero-DR Assay results

Multiplexing of Allplex™ Entero-DR Assay allows to detect 3 major antibiotic resistant bacteria (CPE, VRE, and ESBL) in a single run and provides individual Ct values for each resistance gene.

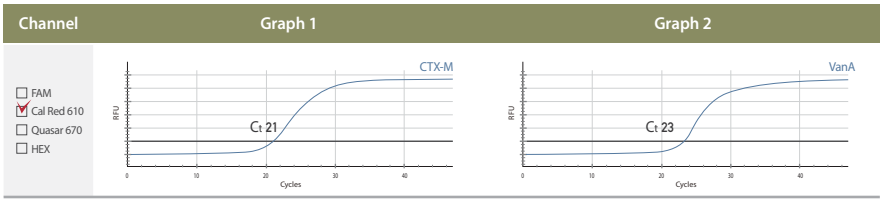
CPE patient

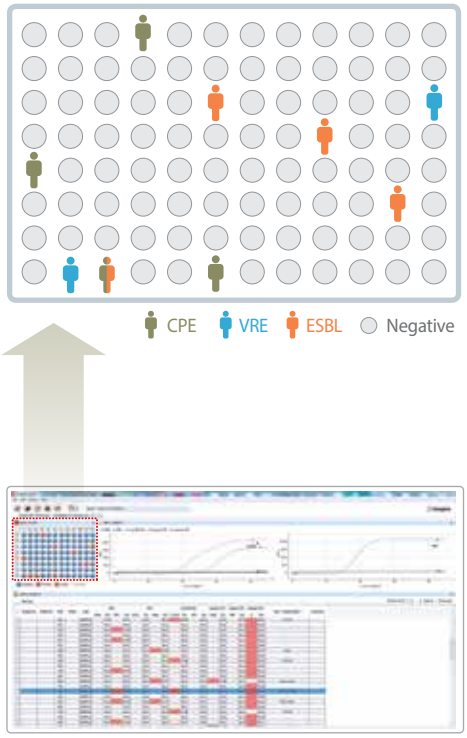


VRE patient



VRE+ESBL patient





Needs for CPE/VRE/ESBL screening [1-6]

Who to screen	VRE (Gram-positive)	CPE/ESBL (Gram-negative)
Exposure to intensive care unit(ICU)	●	●
Previous carriage with VRE or CPE/ESBL	●	●
Exposure to long-term care setting	●	●
Use of urinary/intravenous catheter	●	●
Exposure to transplantation wards	●	●
Exposure to dialysis unit	●	●
Elderly age group	●	●
Compromised immune system	●	●
Use of ventilation		●

CPE, VRE, and ESBL screenings are advised to routinely manage and control patients at high-risks of infections.

1) SA Health. Vancomycin-resistant enterococci (VRE): Infection Prevention and Control Clinical Guideline. 2020: Government of South Australia. 1-25 p.

2) CDC. Facility Guidance for Control of Carbapenem-resistant Enterobacteriaceae (CRE). 2015: CDC. 1-24 p.

3) Vancomycin-resistant Enterococci (VRE) in Healthcare Settings. CDC; Available from https://www.cdc.gov/hai/organisms/vre/vre.html

4) Lim YK, Lee MK, Kim TH. Management of Extended-Spectrum Beta-Lactamase-Positive Gram-Negative Bacterial Urologic Infections. Urogenital Tract Infection. 2015;10(2):84.

5) Valenza G, et al. Screening of ESBL-producing Enterobacteriacae concomitant with low degree of transmission in intensive care and bone marrow transplant units. Infect Dis (Lond). 2017;49(5):405-409.

6) ESCMID training course. ESCMID; Available from https://www.escmid.org/escmid_publications/escmid_elibrary/material/?mid=29308.

Ordering information

Product	Size	Cat. No.
Allplex™ Entero-DR Assay	100 rxns* 25 rxns	CR9700X CR10384Z

* For use with Seegene NIMBUS and Seegene STARlet

Instrument	Cat. No.
CFX96™ Dx	1845097-IVD 1841000-IVD
Seegene NIMBUS	65415-03
Seegene STARlet	67930-03
Seegene STARlet-AIOS	SG72100
SEEPREP32™	SG71100
Maelstrom™ 9600*	M9600

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