ENGLISH

CE-IVD Marked

World's 1st technology

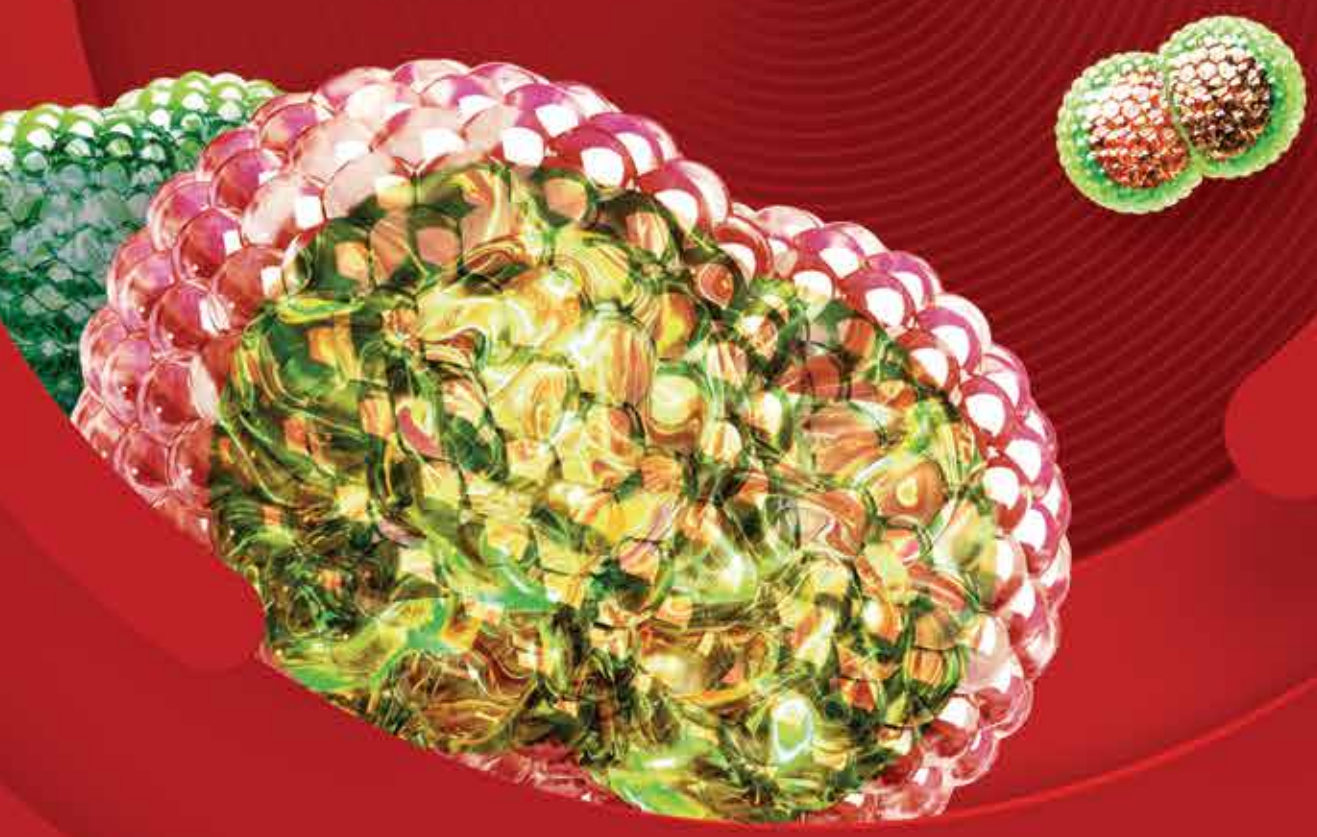
Individual Ct value of multiple analyte in a single channel

Allplex™

Meningitis Panel Assays

Essential screening assay for the detection and identification of 18 meningitis pathogens using multiplex one-step Real-time RT-PCR

6 Bacteria / 12 Viruses



Superior

HIGH SENSITIVITY & SPECIFICITY

Multiplex real-time PCR with high sensitivity and specificity by utilization of DPO™ and TOCE™ technologies

Seegene

REAL TIME PCR | CE-IVD Marked

Allplex™ Meningitis Panel Assays

Essential screening assay for the detection and identification of 18 meningitis pathogens using multiplex one-step Real-time RT-PCR

Viral and bacterial infections are the most common cause of meningitis. There are many difficulties distinguishing bacterial meningitis from viral meningitis by symptoms. However, it is important to diagnose the specific cause of meningitis because the treatment differs depending on the cause. Inability to distinguish between partially treated bacterial meningitis and viral meningitis can lead to unnecessarily prolonged antibiotic treatment and increased duration of hospital admissions.

The cerebrospinal fluid (CSF) culture and Gram stain are typically used for diagnosis of meningitis. However, sensitivity of these methods is limited, particularly when patients receive antimicrobial treatment prior to CSF collection. The use of real-time PCR can improve sensitivity for detection of meningitis pathogens and also multiplex real-time PCR allows simultaneous detection of multiple pathogens in a single reaction.

Allplex™ Meningitis Panel Assays are a multiplex one-step Real-time RT-PCR assay that detects and identifies 18 meningitis pathogens including 6 bacteria and 12 viruses simultaneously. Based on Seegene's proprietary MuDT™ technology, this assay makes it possible to report multiple C_t values of each pathogen in a single channel without melting curve analysis.

Specimen

- Cerebrospinal fluid (CSF)

Key features

- Simultaneous detection and identification of 12 viruses and 6 bacteria causing meningitis
- Multiplex one-step real-time RT- PCR assay within 2 hours after extraction
- Individual C_t values for multiple targets in a single reaction
- Flexible choices of target pathogens based on panels for effective patient care
- Providing whole process control for assay validity
- Automated data interpretation with Seegene Viewer

Compatible instrumentation (CE-IVD Marked)

- **Auto Extraction & PCR Setup**
  Seegene NIMBUS
  Seegene STARlet
- **Auto Extraction**
  NucliSENS® easyMAG® (BioMérieux)
- **Real-time PCR**
  CFX96™ Dx

Analytes

1 tube / 1 panel

Panel 1		Panel 2		Panel 3	
Virus (I)		Virus (II)		Bacteria	
- Herpes simplex virus type 1	- Herpes simplex virus type 2	- Parvovirus B19	- Adenovirus	- *Haemophilus influenzae*	- *Neisseria meningitidis*
- Varicella-zoster virus	- Epstein-barr virus	- Mumps virus	- Enterovirus	- *Streptococcus pneumoniae*	- Group B *Streptococcus*
- *Cytomegalovirus*	- Human herpesvirus 6	- Parechovirus	- Internal Control (IC)	- *Listeria monocytogenes*	- *E.coli* K1
- Human herpesvirus 7	- Internal Control (IC)			- Internal Control (IC)	

Why molecular test is needed?

Comparison of gram stain, bacterial culture and multiplex PCR for detection of five bacteria* in CSF samples.[2)]

Bacteria culture	Gram stain	Multiplex PCR	N=110
+	+	+	8
-	+	-	1
+	-	-	0
-	**-**	**+**	**50**
+	+	-	0
-	+	+	2
+	-	+	0
-	-	-	49

S. pneumoniae, H. influenzae type b, *N. meningitides*, Group B *streptococcus*, and *L. monocytogenes*

50 patients (45.5%) were diagnosed as acute bacterial meningitis by multiplex PCR test, while both bacterial culture and gram stain test results were negative.[2)]

Culture/Gram stain is affected by prior antimicrobial therapy.

- Yield of CSF Gram stain may be ~20% lower for patients who received prior antimicrobial therapy.[1)]
- Antimicrobial therapy can reduce bacterial load of CSF culture to undetectable levels within 1 hour.[1)]

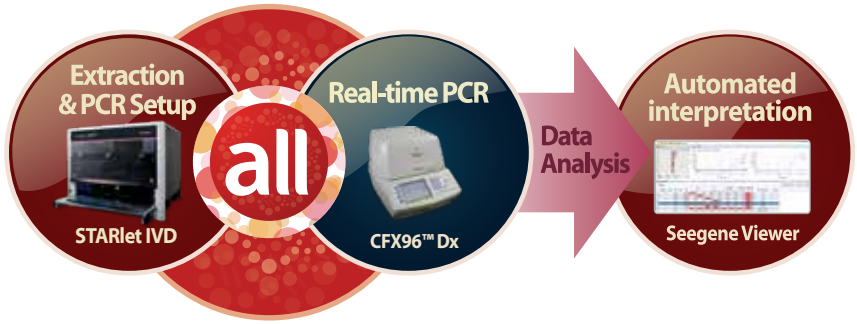
Culture/Gram stain has relatively low sensitivity.

- Lead to low rate of positive result.

1) Practice guidelines for the management of bacterial meningitis(IDSA, 2004)
2) Comparison of multiplex PCR, gram stain, and culture for diagnosis of acute bacterial meningitis Int J pharm pharm Sci, Issue 6, Vol. 6, No. 4, 2014

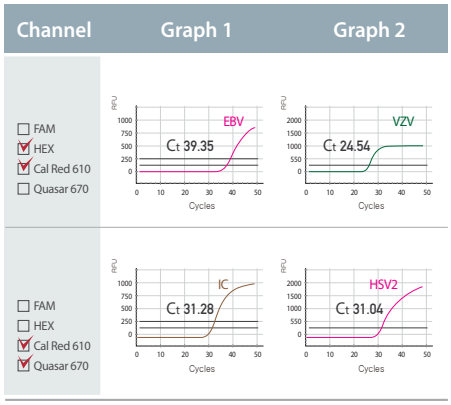
Seegene's Powerful Automation Platform for Complete Test Process

Convenient total workflow using Seegene's automation platform



- 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™ Meningitis-virus(I) Assay



The result represents co-infection of EBV, VZV and HSV2 in Cal Red 610 and HEX channel with Ct values of 39.35 (Graph 1) and 24.54 (Graph 2), 31.04 (Graph 2) respectively. Allplex™ Meningitis Virus(I) Assay is able to provide the information of meningitis pathogens by analyzing individual Ct value using Seegene Viewer.

Why do we focus on meningitis?

Every year **more than 1.7 million people** worldwide suffer from meningitis and **0.17million people die by bacterial meningitis**[1)]

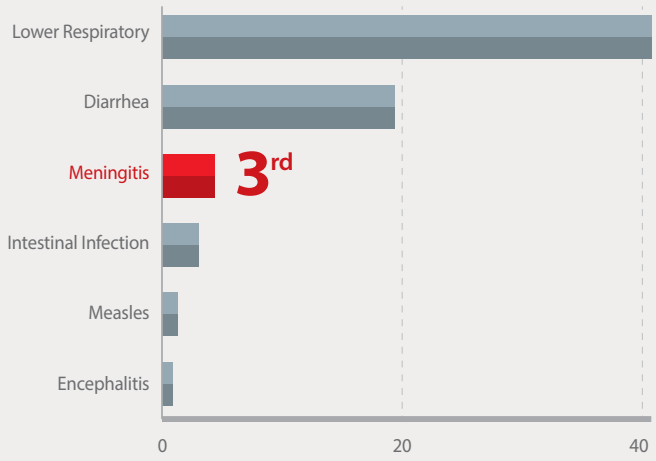
10% Approximately 10% of patients die[2)]

20% 20% of survivors suffer from permanent debilitation[2)]
(Hearing loss, brain damage, loss of limbs, other serious effects)

50% Overall about 50% bacterial meningitis occurs in children under the age of five years[1)]

Meningitis 3rd
highest mortality rate in infectious diseases

Annual Mortality Rate (per 100,000 people) [3)]



1) CONFEDERATION OF MENINGITIS ORGANISATIONS INC. 2) CDC 3) Institute for Health metrics and evaluation

Clinical significance of meningitis causative pathogens

Bacterial Meningitis

Highly contagious & common prevalent pathogens

Haemophilus influenzae
- Predominantly seen in children with a mortality rate of 3-6% [1)]

Neisseria meningitidis
- Frequently seen in developing countries [2), 3)]

Streptococcus pneumoniae
- Frequently seen in pediatric, elderly and HIV-positive patients [4), 5)]

Group B *Streptococcus*
- Significant cause of meningitis in neonates [6), 7)]

Listeria monocytogenes
- High mortality rate even with early antibiotic treatment [8)]

Viral Meningitis

Highly contagious & prevalent pathogens

Enterovirus
- Responsible of most viral meningitis during summer [9)]

Herpes simple virus (HSV-1, HSV-2)
- Common cause of CSF infections [10), 11)]

Human herpesvirus-6 (HHV-6)
- Shows latency with primary infection at childhood [12), 13)]

Vericella Zoster Virus (VZV)
- Can reactivate later in life and may lead to progressive neuronal deterioration [14), 15)]

Epstein-Barr Virus (EBV/HHV-4)
- Predominantly seen in children with no symptoms [16), 17)]

***Cytomegalovirus* (CMV)**
- Ubiquitously seen in immunocompromised patients [18), 19), 20)]

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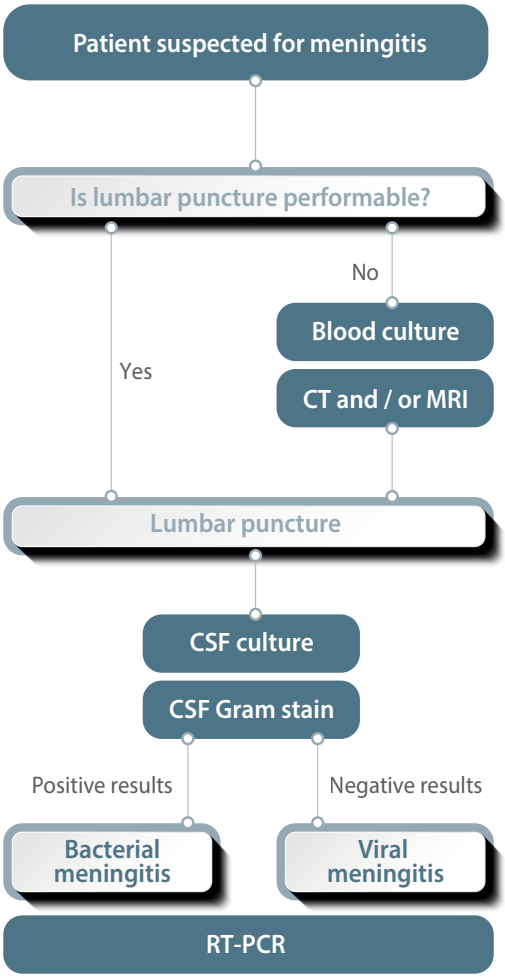
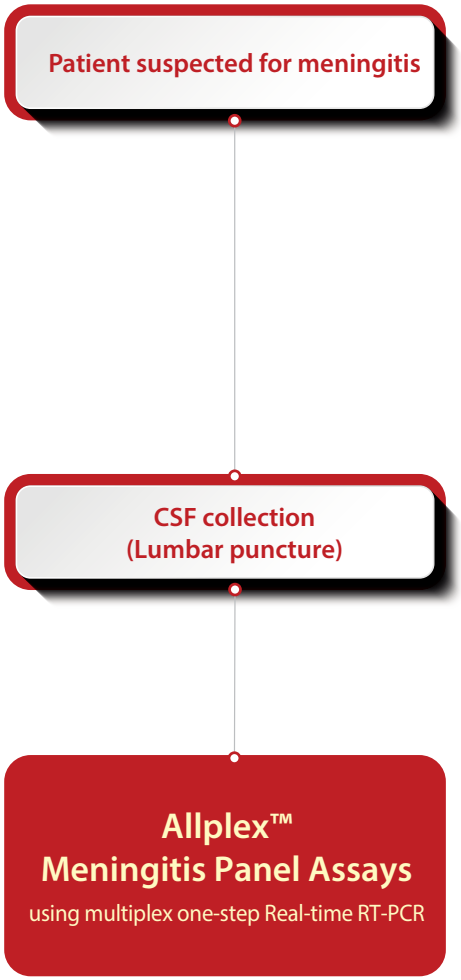
Efficient diagnosis for better patient's outcome





Solution for unmet needs

Conventional diagnosis		Molecular diagnosis
- Unable to fully differentiate between viral and bacterial infections	Differentiation	- Able to distinguish bacterial from viral meningitis by a single test
- Diagnostic yields are lower in patients who have received antimicrobial therapy prior to lumbar puncture	Accuracy	- Not affected by antimicrobial therapy
- Relatively low	Sensitivity	- Relatively High
- Requires at least a day or more - Unable to early diagnosis and treatment	Turn-around time (TAT)	- Short TAT
- Subjective interpretation	Result	- Automated data interpretation by Seegene viewer S/W

Allplex™ Meningitis Panel Assays prevents unnecessary antibiotic therapy and hospitalization by quick and accurate diagnosis of different types of meningitis with one single test.

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Key features

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Ordering Information

Category	Product	Package Volume	Cat. No.
Allplex™	**Meningitis-V1 Assay**	25 rxns*	MG10209Z
		50 rxns	MG9700Y
		100 rxns*	MG9700X
Allplex™	**Meningitis-V2 Assay**	25 rxns*	MG10210Z
		50 rxns	MG9500Y
		100 rxns*	MG9500X
Allplex™	**Meningitis-B Assay**	25 rxns*	MG10211Z
		50 rxns	MG9600Y
		100 rxns*	MG9600X

* 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	65415-03
STARlet IVD (Microlab STARlet IVD)	Automated extraction & PCR Setup	67930-03
STARMag 96 X 4 Universal Cartridge kit	Nucleic acids extraction reagent	744300.4.UC384

Seegene

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