ENGLISH

CE-IVD Marked

World's 1st technology

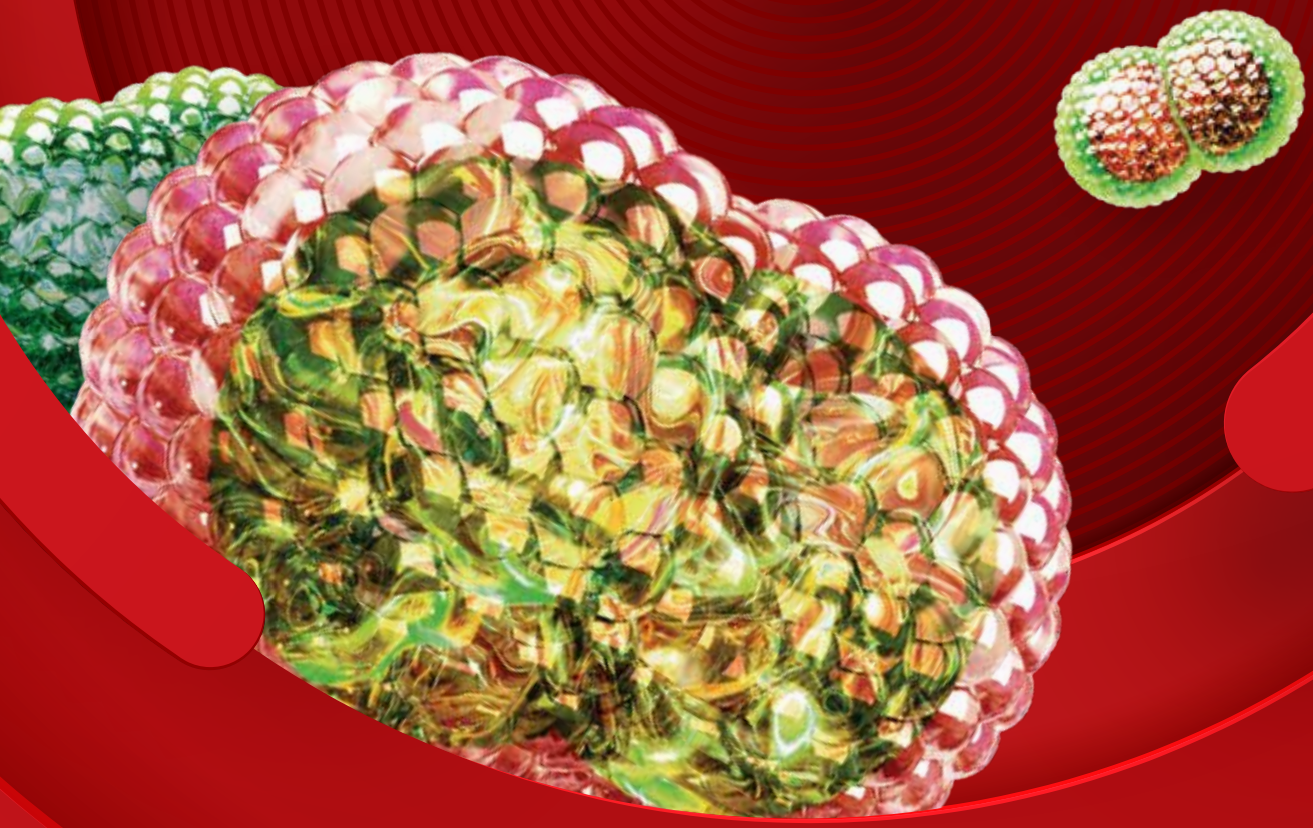
Individual Ct value of multiple analyte in a single channel

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)]

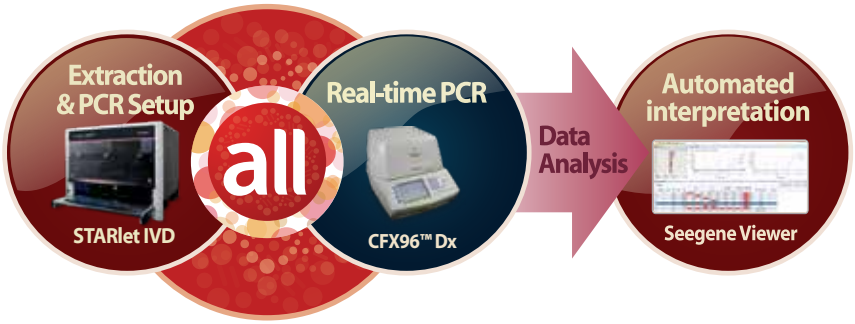
**Culture/Gram stain has relatively low sensitivity.**

- 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

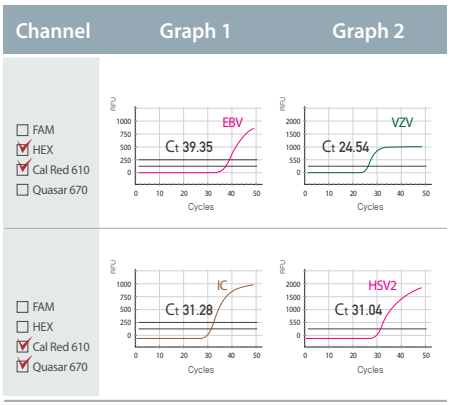
## Seegene's Powerful Automation Platform for Complete Test Process

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)]

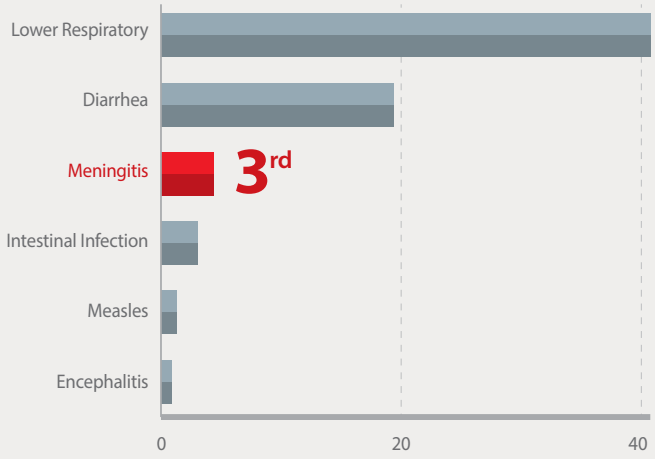
**10%** Approximately 10% of patients die[2)]

**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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17) Kutok J., Wang F. (2006) Spectrum of Epstein–Barr virus-associated diseases. Annu Rev Pathol 1: 375–404
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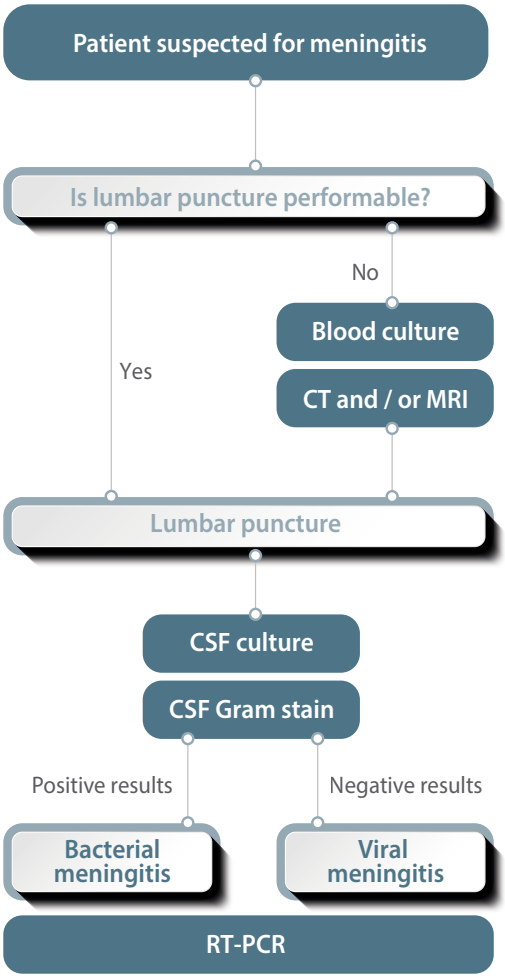
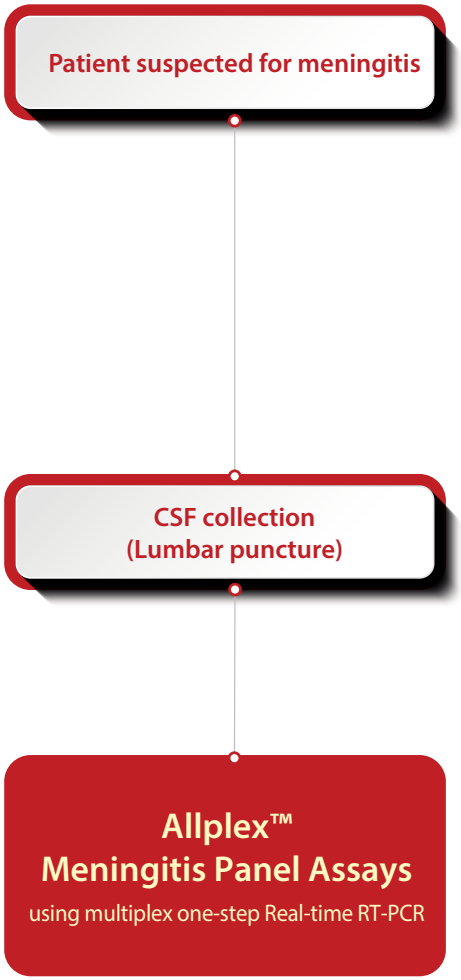
## Efficient diagnosis for better patient's outcome




## 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<br>- 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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# Meningitis Panel Assays

## 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 Ct values for multiple targets in a single reaction
- Flexible choices of target pathogens based on panels for effective patient care
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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 |


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