Xpert™ EV

The only molecular in vitro diagnostic Enteroviral meningitis test.

defining on-demand molecular diagnostics.
Enteroviruses are the most common cause of meningitis in the US, resulting in an estimated 30,000 to 50,000 hospitalizations per year. Most cases of meningitis are caused by infectious agents, primarily bacteria and viruses. Bacterial meningitis is generally more severe and potentially more life threatening. The viral form usually self-resolves within 7–10 days and accounts for the majority of cases overall. Currently, when a patient presents with meningitis-like symptoms, a spinal tap is performed and the cerebral spinal fluid is cultured to determine the etiology. Patients are often treated empirically with antibiotics, and possibly antiviral drugs, until bacteria and viral cultures become available in two to three days. Isolation of EV, from CSF, requires 2–3 days or longer — and results are rarely rapid enough to affect patient management.

**solution:**
Introducing Cepheid’s Xpert™ EV, the only molecular in vitro diagnostic test that delivers results in about 2.5 hours. When Xpert EV results are used in conjunction with standard laboratory results (for CSF Gram stain, CSF bacterial culture, CSF glucose, CSF blood glucose ratio, CSF total protein concentration, and CSF leukocyte count) physicians can confidently identify patients with EV and manage them appropriately instead of just treating symptoms.

**impact:**
The impact of Cepheid’s Xpert EV is substantial: identifying those patients with Enterovirus and helping to rule out bacterial meningitis quickly allows for appropriate management of patients. Timely answers provide assurance to patients and their families to reduce anxiety.

**problem:**
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**integrated:**
The GeneXpert® is the only system to combine sample preparation with real time PCR amplification and detection for fully integrated and automated nucleic acid analysis. The system purifies, concentrates, detects, and identifies targeted nucleic acid sequences in about 2.5 hours.

**flexible:**
The GeneXpert System’s unique random access capability enables users to perform from one to 16 molecular tests concurrently. And because runs can be started at different times, multiple operators can easily use the GeneXpert System simultaneously. With the GeneXpert System, the days of inefficient batch processing are finally over. Specimens can now be processed on demand — 24 hours a day, 365 days a year.

**easy to use:**
The GeneXpert System requires minimal hands-on time. Users simply insert the biological sample for testing in a self-contained cartridge and the GeneXpert System does the rest.
## Sensitive and Specific:
Provide the best patient management decisions.

<table>
<thead>
<tr>
<th>GeneXpert®</th>
<th>Clinical Diagnosis</th>
<th>+</th>
<th>-</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>+</td>
<td>26</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>-</td>
<td>1</td>
<td>103</td>
</tr>
<tr>
<td>Totals</td>
<td></td>
<td>27</td>
<td>106</td>
</tr>
</tbody>
</table>

**Sensitivity:** 96.3%, 95%, CI 81-99.9%

**Specificity:** 97.2%, 95%, CI 91.9-99.4%

## Reproducible:
Confidence and consistency in your results.

### Table 2: Summary of reproducibility results

<table>
<thead>
<tr>
<th>Specimen ID</th>
<th>Total Agreement — Ct Results</th>
<th>Total % Agreement</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Day 1</td>
<td>Day 2</td>
</tr>
<tr>
<td>Negative</td>
<td>20/20</td>
<td>18/18&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>CA9 2X LOD</td>
<td>4/5&lt;sup&gt;a&lt;/sup&gt;</td>
<td>5/5</td>
</tr>
<tr>
<td>CA9 4X LOD</td>
<td>5/5</td>
<td>5/5</td>
</tr>
<tr>
<td>EV70 2X LOD</td>
<td>5/5</td>
<td>5/5</td>
</tr>
<tr>
<td>EV70 4X LOD</td>
<td>5/5</td>
<td>5/5</td>
</tr>
<tr>
<td>Number of Instruments Used</td>
<td>10</td>
<td>11</td>
</tr>
<tr>
<td>Number of Modules Used</td>
<td>40</td>
<td>41</td>
</tr>
</tbody>
</table>

<sup>a</sup> Total runs = 21, 2 - no result, 1 - invalid
<sup>b</sup> Total runs = 5, 1 - negative instead of positive result
<sup>c</sup> Total runs = 5, 1 - invalid
<sup>d</sup> Total runs = 5, 1 - no result

Two representative whole virus subtypes (i.e., Coxsackievirus CVA9 and Enterovirus EV70) were spiked into human negative CSF to create simulated specimens at both 2 x LoD and 4 x LoD. Negative samples were tested 20 times while positive samples at the different concentrations 5 times per day. Of the total samples tested, there were two samples with “Invalid” and three samples with “No Result” by instrument software control definitions. Of the 157 reportable results, 155 were correctly classified.

## Comprehensive:
Complete coverage of significant serotypes.

### Table 3: Enterovirus serotypes detected by the Xpert™ EV Assay:

<table>
<thead>
<tr>
<th>Species</th>
<th>Serotypes</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Coxsackie A2-A8, A10, A12, A14, A16, EV71</td>
</tr>
<tr>
<td>B</td>
<td>Coxsackie A9, B1-B6, Echo 1-7, 9, 11-21, 24-27, 29-33, EV69</td>
</tr>
<tr>
<td>C*</td>
<td>Coxsackie A11, A13, A15, A17-22, A24</td>
</tr>
<tr>
<td>D</td>
<td>EV68, EV70</td>
</tr>
<tr>
<td>Poliovirus</td>
<td>Poliovirus 1-3</td>
</tr>
</tbody>
</table>

<sup>*</sup>Coxsackie A1 not available for testing

**CAUTION:** The results obtained with the Xpert EV assay should be used only as an adjunct to clinical observation and other information available to the physician. Positive Xpert EV results do not rule out other causes of meningitis, including bacteria, mycobacteria, other viruses (e.g., herpes family viruses, arboviruses, mumps virus, etc.) and fungi.
The Xpert™ EV advantage: Simplicity

- Fully automated process reduces handling time to just minutes
- Random access for flexibility and workflow optimization
- Rapid results to improve patient management
- Fully integrated reagent and instrument system for accuracy and reproducibility

1. Dispense Binding Reagent into port 1

2. Dispense Wash Reagent into port 2

3. Dispense Elution Reagent into port 3

4. Add 140µl of Lysis Reagent into port 4S

5. Add 140µl of Sample into port 4S

6. Insert cartridge and start assay

Total hands-on time = 5 minutes

Ordering Information

Xpert™ EV

Catalog No. GXEV-100N-10
(10 cartridges with reagents)

References:


Armored RNA® is a patented technology jointly owned by Asuragen Inc and Cenetron Diagnostics, LLC under US Patents Nos. 5,677,124, 5,919,625, 5,939,262, and other patents pending.

The purchase of this product includes a limited, non-transferable license under U.S. Patents Nos. 6,787,338; 6,503,720 and 6,303,305, and claims 9, 10, 11, 56, 76, 80 and 107 of U.S. Patent No. 6,174,670, and corresponding claims in patents and patent applications outside the United States, owned by the University of Utah Research Foundation and licensed to Idaho Technology, Inc, to use only this amount of product and only in an instrument marketed, distributed, sold, leased or otherwise transferred using a Cepheid trademark. No right is conveyed, expressly, by implication or estoppel, under any other patent or patent claims owned by the University of Utah Research Foundation or Idaho Technology, Inc. The purchase of this product allows the purchaser to use it for the performance of diagnostic services for human in vitro diagnostics. No general patent or other license of any kind other than this specific right of use from purchase is granted hereby.

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