Xpert® EV

The only rapid molecular in vitro diagnostic Enteroviral meningitis test.
Knowing whether the meningitis is viral or bacterial is imperative to early effective treatment. Because Xpert® EV is significantly faster than existing methods for diagnosing meningitis, it could minimize delays in treating patients. Swift recognition of the cause and appropriate treatment is critical to patient recovery.”

Adopted from FDA News
P07-46, March 16, 2007

THE NEED
Enterovirus (EV) meningitis is very common among young children, but very difficult to differentiate from bacterial meningitis due to similar clinical presentations. As a result, patients are often admitted and treated empirically.

- EV meningitis is estimated to cause 30,000 to 50,000 hospitalizations annually in the US
- EV meningitis is usually self-limiting and does not require antibiotic treatment
- EV meningitis and bacterial meningitis are very difficult to differentiate by symptoms alone
- Suspected meningitis patients are often admitted and treated empirically
- Empirical treatment of suspected meningitis patients are costly for hospitals

THE SOLUTION
Rapid and accurate detection of enterovirus from the Central Spinal Fluid (CSF) specimen enables establishment of an effective patient management pathway.

- Rapid and accurate EV result in about 2.5 hours is clinically actionable
- Physicians can confidently identify patients with EV meningitis and manage them appropriately instead of empirical treatment
- Timely answers provide assurance to patients and their families to reduce anxiety
SENSITIVE AND SPECIFIC

Provide the best patient management decisions.

Prospective clinical samples evaluated against “Clinical Diagnosis”

<table>
<thead>
<tr>
<th></th>
<th>Clinical Diagnosis +</th>
<th>Clinical Diagnosis –</th>
</tr>
</thead>
<tbody>
<tr>
<td>GeneXpert&lt;sup&gt;®&lt;/sup&gt; +</td>
<td>26</td>
<td>3</td>
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<tr>
<td>GeneXpert&lt;sup&gt;®&lt;/sup&gt; –</td>
<td>1</td>
<td>103</td>
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<tr>
<td>Totals</td>
<td>27</td>
<td>106</td>
</tr>
</tbody>
</table>

*Sensitivity: 96.3%, 95%; CI 81.0–99.9%
*Specificity: 97.2%, 95%; CI 91.9–99.4%

Banked prospectively collected clinical samples evaluated against “Clinical Diagnosis”

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<tr>
<td>GeneXpert&lt;sup&gt;®&lt;/sup&gt; +</td>
<td>23</td>
<td>3</td>
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<tr>
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<td>96</td>
</tr>
<tr>
<td>Totals</td>
<td>23</td>
<td>99</td>
</tr>
</tbody>
</table>

*Sensitivity: 100%, 95%; CI 85.2–100%
*Specificity: 97%, 95%; CI 91.4–99.4%

COMPREHENSIVE

Complete coverage of significant serotypes.

Enterovirus serotypes detected by the Xpert<sup>®</sup> EV

<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>
</tbody>
</table>

| Poliovirus | Poliovirus 1-3 |

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.

*Coxsackie A1 not available for testing

ANSWER YOU NEED IN 3 HOURS OR LESS

Xpert EV provides useful and timely information to clinicians for improved patient management.

Min 00’ --------- 30’ --------- 45’ --------- 150’ --------- 180’

Patient Suspected of Meningitis

Specimen Taken and Sent for Hospital Near Patient Testing

Specimen Run on GeneXpert<sup>®</sup> System With Results in Less Than 2.5 Hours

Floor Receives Results Indicating:
• EV Positive
• Negative

Optimal Patient Management Decision
WORKFLOW:
6 EASY STEPS
Total hands-on time: <5 Minutes

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

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. Without limiting the foregoing, no right, title or license is herein granted with respect to the uses that are proprietary to Idaho Technology or the University of Utah Research Foundation of fluorescent double stranded nucleic acid binding dyes, specifically including but not limited to SYBR® Green I, LCGreen® I, or LCGreen® Plus. Licensed under U.S. Patent Nos. 5,075,212 and EP 0465603B1.

For In Vitro Diagnostic Use.