

A photograph of a woman with brown hair, wearing a light-colored top, holding a young child with dark hair and a yellow shirt. They are sitting on a grey couch in what appears to be a hospital or clinic setting. The background is slightly blurred, showing medical equipment and a computer monitor.

Xpert[®]
EV

 Xpert[®] EV

The only rapid molecular *in vitro* diagnostic
Enteroviral meningitis test.

 Cepheid[®]
A better way.

“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.

TABLE 1A: PROSPECTIVE CLINICAL SAMPLES EVALUATED AGAINST “CLINICAL DIAGNOSIS”

| | | Clinical Diagnosis | |
|------------|---|--------------------|-----|
| | | + | - |
| GeneXpert® | + | 26 | 3 |
| | - | 1 | 103 |
| Totals | | 27 | 106 |

SENSITIVITY: **96.3%, 95%; CI 81.0-99.9%**
 SPECIFICITY: **97.2%, 95%; CI 91.9-99.4%**

TABLE 1B: BANKED PROSPECTIVELY COLLECTED CLINICAL SAMPLES EVALUATED AGAINST “CLINICAL DIAGNOSIS”

| | | Clinical Diagnosis | |
|------------|---|--------------------|----|
| | | + | - |
| GeneXpert® | + | 23 | 3 |
| | - | 0 | 96 |
| Totals | | 23 | 99 |

SENSITIVITY: **100%, 95%; CI 85.2-100%**
 SPECIFICITY: **97%, 95%; CI 91.4-99.4%**

Comprehensive

Complete coverage of significant serotypes.

TABLE 3: ENTEROVIRUS SEROTYPES DETECTED BY THE XPERT® EV ASSAY

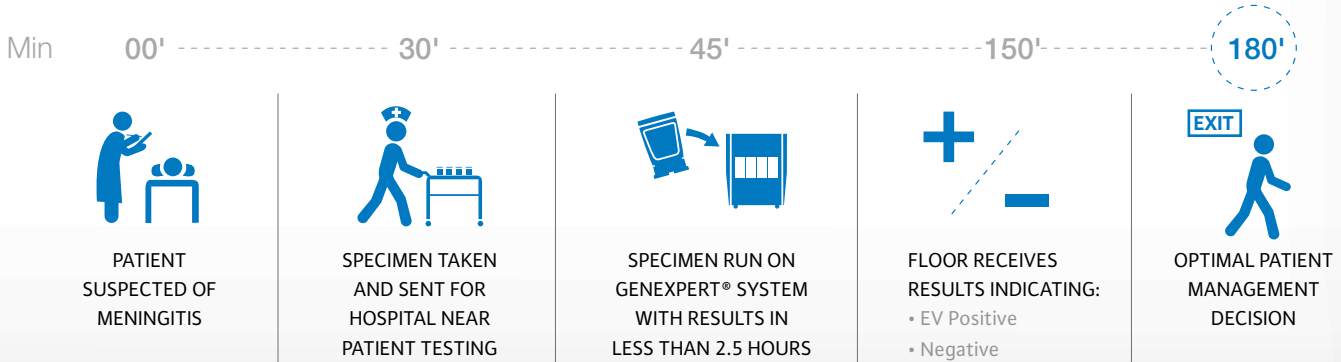
| Species | Serotypes |
|------------|---|
| A | Coxsackie A2-A8, A10, A12, A14, A16, EV71 |
| B | Coxsackie A9, B1-B6, Echo 1-7, 9, 11-21, 24-27, 29-33, EV69 |
| C* | Coxsackie A11, A13, A15, A17-22, A24 |
| D | EV68, EV70 |
| Poliovirus | Poliovirus 1-3 |

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.









Simplicity Xpert® EV

- 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

WORKFLOW:

6 Easy Steps

Total hands-on time: <5 Minutes

| | | | | | |
|---|--|---|---|---|---|
| <p>1</p> <p>Dispense Binding Reagent into Port 1</p>  | <p>2</p> <p>Dispense Wash Reagent into Port 2</p>  | <p>3</p> <p>Dispense Elution Reagent into Port 3</p>  | <p>4</p> <p>Add 140µl of Lysis Reagent into Port 4S</p>  | <p>5</p> <p>Add 140µl of Sample into Port 4S</p>  | <p>6</p> <p>Insert cartridge and start assay</p>  |
|---|--|---|---|---|---|

ORDERING INFORMATION

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

References:

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4. Robinson CC, Willis M, Meagher A, et al. Impact of rapid polymerase chain reaction results on management of pediatric patients with enteroviral meningitis. *Pediatric Infectious Disease Journal.* 2002; 21: 283-6.
5. Cost Savings Through Rapid Diagnosis of Enteroviral Meningitis. *Pediatric Infectious Disease Journal.* 2004
6. Ramers C, Billman G, Hartin M, Ho S, Sawyer M. Impact of a Diagnostic Cerebrospinal Fluid Enterovirus Polymerase Chain Reaction Test on Patient Management. *IAMA.* 2000; 283, 20

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