Performance Characteristics of the Access® Cytomegalovirus (CMV) Immunoglobulin M (IgM) Assay

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Abstract

Cytomegalovirus (CMV) is a member of the Herpesvirus family and is found throughout the world. The seroprevalence of human CMV virus ranges from 30% to 90% in developed countries, with an increasing prevalence with age. Transmission of the infection occurs through sexual contact, direct exposure to infected body fluids, blood transfusions, and organ transplantations. Primary infection is usually asymptomatic in healthy individuals, after which the virus establishes lifelong latency and periodically reactivates. CMV infection rarely causes complications in healthy individuals, but can cause severe disease in immunocompromised individuals and newborns. Primary infection occurs in utero, newborns, transplant recipients, and immunocompromised patients. All samples were tested by the Access 2 and mini VIDAS methods. The mini VIDAS was used as the comparison method.

Table 2. Concordance summary of samples submitted to the clinical laboratory for routine maternal serum testing

<table>
<thead>
<tr>
<th>Method</th>
<th>Positive</th>
<th>Negative</th>
<th>Equivocal</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Access 2 CMV IgM</td>
<td>55</td>
<td>26</td>
<td>48</td>
<td>129</td>
</tr>
<tr>
<td>mini VIDAS IgM</td>
<td>54</td>
<td>25</td>
<td>51</td>
<td>130</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Method</th>
<th>Positive</th>
<th>Negative</th>
<th>Equivocal</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accurate Cut-off</td>
<td>0.145</td>
<td>0.0</td>
<td>0.0</td>
<td>0.145</td>
</tr>
<tr>
<td>VIDAS®</td>
<td>0.145</td>
<td>0.0</td>
<td>0.0</td>
<td>0.145</td>
</tr>
</tbody>
</table>

Table 3. Concordance summary of pregnancy samples submitted to the clinical laboratory for routine maternal serum testing

<table>
<thead>
<tr>
<th>Method</th>
<th>Positive</th>
<th>Negative</th>
<th>Equivocal</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Access 2 CMV IgM</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>mini VIDAS IgM</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>

Table 4. Concordance summary of immunocompromised samples from Emory University Hospital

<table>
<thead>
<tr>
<th>Method</th>
<th>Positive</th>
<th>Negative</th>
<th>Equivocal</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Access 2 CMV IgM</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>mini VIDAS IgM</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>

Table 5. Concordance summary of transplant samples from Emory University Hospital

<table>
<thead>
<tr>
<th>Method</th>
<th>Positive</th>
<th>Negative</th>
<th>Equivocal</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Access 2 CMV IgM</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>mini VIDAS IgM</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>

Materials and Methods

• Method comparison studies were performed using 1046 specimen that had previously been submitted to the clinical laboratory for CMV IgM testing. Specimens consisted of 441 males and 605 females between the ages of 18 and >89 years old. All samples were tested by the Access 2 and mini VIDAS. The mini VIDAS was used as the comparison method.

• Serum specimens from 307 females ages 18 to 45 years who were in their 2nd trimester Positive Negative 35 441 1 442

• De-identified serum samples from 75 immunocompromised subjects were sent from Emory University Hospital. The sample population consisted of 44 males and 31 females ages 20 – 88 years old. Serum specimens from 216 transplant recipient samples were sent from Emory University Hospital. The sample population consisted of 123 males and 32 females ages 20 – 88 years old.

• De-identified serum samples from 1046 specimen that had previously been submitted to the clinical laboratory for CMV IgM testing. Specimens consisted of 441 males and 605 females between the ages of 18 and >89 years old. All samples were tested by the Access 2 and mini VIDAS. The mini VIDAS was used as the comparison method.

Results and Conclusions

• Total imprecision was acceptable for the Access 2 and mini VIDAS CMV IgM methods. The Access 2 demonstrated CVs ≤5.9% for all control levels and the mini VIDAS demonstrated CVs ≤5.8% for all control levels.

• Concordance analyses for the Access 2 method using routine CMV IgM samples sent to the clinical laboratory showed 96.6% agreement compared to the mini VIDAS CMV IgM method.

• For pregnancy samples sent to the clinical laboratory for routine maternal serum testing, concordance analyses showed 99.7% agreement for the Access 2 CMV IgM method compared to the mini VIDAS CMV IgM method.

• The Access 2 CMV IgM method demonstrated 97.2% agreement with the mini VIDAS CMV IgM method using immunocompromised serum samples.

• For samples from transplant patients, concordance analyses demonstrated 99.0% agreement for the Access 2 CMV IgM method compared to the mini VIDAS CMV IgM method.

• The Access 2 method showed good analytical performance compared to the mini VIDAS method and is suitable for routine clinical testing.

Acknowledgements

This work was supported by Beckman Coulter, Inc. and the ARUP Institute for Clinical and Experimental Pathology®. An Access 2 analyzer was provided by Beckman Coulter, Inc.

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