Although rarely pathogenic in immunocompetent individuals, cytomegalovirus (CMV) causes severe morbidity and mortality in congenitally infected newborns and immunocompromised patients.

This study evaluates the analytical performance and the clinical utility of a novel molecular test, Q-LAMP lam CMV (DiaSorin), in the diagnosis of active human CMV infection.

**MATERIAL AND METHODS**

This study was carried out with the Laboratory of Virology in Toulouse. Here it is shown a part of the project we carried out.

In the first phase, a pre-market evaluation of Q-LAMP lam CMV analytical performance on LIAISON®/LIAISON Immunoassay Instruments (Figure 1) was performed; in particular 8 clinical samples and 35 artificial standards were tested.

In the second phase, 120 clinical samples were processed to evaluate the clinical utility of the Q-LAMP lam CMV. Fifty urine and 50 plasma samples were collected from 76 individuals during active CMV infection: 20 urine and 20 plasma from 34 pregnant women with primary/non primary infection; 20 urine and 20 plasma from 18 immunocompetent patients with symptomatic CMV primary infection and lastly, 20 plasma from 4 hematopoietic stem cells transplant (HSCT) recipients. Ten urine and 10 plasma samples were collected from uninfected pregnant women, immunocompetent patients and newborns.

**RESULTS**

**First phase**

**Table 1. Comparison of results obtained by our laboratory and by DiaSorin Laboratory**

<table>
<thead>
<tr>
<th>Expected results</th>
<th>Obtained results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>35</td>
</tr>
<tr>
<td>Negative</td>
<td>8</td>
</tr>
<tr>
<td>Total</td>
<td>43</td>
</tr>
</tbody>
</table>

The results from our laboratory were compared with those obtained in the same samples at the DiaSorin laboratory (expected results). A good agreement (100%) was demonstrated (Table 1).

Figure 2. Comparison of viral loads obtained from positive samples and expected values

A good correlation (R²=0.80) with the quantitative values was demonstrated by linear regression (Figure 2).

Following this, 120 clinical samples were processed to evaluate the clinical utility of the Q-LAMP lam CMV. Fifty urine and 50 plasma samples were collected from 76 individuals during active CMV infection: 20 urine and 20 plasma from 34 pregnant women with primary/non primary infection; 20 urine and 20 plasma from 18 immunocompetent patients with symptomatic CMV primary infection and lastly, 20 plasma from 4 hematopoietic stem cells transplant (HSCT) recipients. Ten urine and 10 plasma samples were collected from uninfected pregnant women, immunocompetent patients and newborns.

**Second phase**

**Table 2. Q-LAMP lam CMV results in plasma and/or urine samples from 34 pregnant women with primary/non primary infection**

**Table 3. Q-LAMP lam CMV results in urine samples from 20 newborns with congenital CMV infection**

**Table 4. Q-LAMP lam CMV results in plasma samples from 4 HSCT recipients**

**Table 5. Q-LAMP lam CMV results in plasma and/or urine samples from 18 immunocompetent patients**

**CONCLUSION**

- Q-LAMP lam CMV specificity was 100%.
- The assay identified all congenitally infected newborns and actively CMV-infected HSCT recipients.
- The assay may support the serological diagnosis in immunocompetent individuals and in pregnant women with active CMV infection.

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