EVALUATION OF IGG AND IGM ASSAYS ON THE NEW VIDIA® INSTRUMENT AND COMPARISON WITH THE ARCHITECT® AND VIDAS® ASSAYS

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INTRODUCTION

Rubella IgG and IgM assays are especially important in the context of the pregnancy serology, since acute rubella carries a high risk of congenital rubella syndrome in the newborn. Serological status determination is mostly important for women of childbearing age in order to exclude a potential serocconversion during pregnancy. IgG false positivity must be excluded as far as possible.

The aim of the present study was to evaluate the performance of the new Vidia® (Biomérieux) Rubella IgG and IgM assays and to compare it with the performances of automates used in our laboratory (Architect® (Abbott) and Vidas® (Biomérieux) used for confirmation of Architect results).

MATERIAL AND METHODS

Samples: Rubella IgG (IU/mL) and IgM (index) concentrations were measured for 150 sera (whose rubella serology was requested by physician) with the three methods described upper.

Discrepant results in IgG and IgM: The «2 out of 3» statistical method was used to define the IgG serological status and IgG avidity was used for the IgM one (when there were discrepancies between results or to confirm a positive IgM status).

Data analysis: All results equal or higher to the respective thresholds were considered and classified as positive; nevertheless, interpretation of equivocal results in IgG ([threshold; 2x threshold]) is given as « uncertain immunity » in our lab.

RESULTS

Table 1: Summary of the results with the three instruments

<table>
<thead>
<tr>
<th>Sample</th>
<th>Architect® IgM+</th>
<th>Vidas® IgM+</th>
<th>Vidia® IgM+</th>
<th>Sero status</th>
<th>Avidity</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2.5</td>
<td>3.5</td>
<td>3.6</td>
<td>Positive</td>
<td>0.62</td>
<td>Positive Equivocal</td>
</tr>
<tr>
<td>2</td>
<td>2</td>
<td>3</td>
<td></td>
<td>Positive</td>
<td>0.67</td>
<td>Positive Equivocal</td>
</tr>
<tr>
<td>3</td>
<td>1.5</td>
<td>2.4</td>
<td></td>
<td>Negative</td>
<td>0.62</td>
<td>Negative</td>
</tr>
<tr>
<td>4</td>
<td>3.5</td>
<td></td>
<td></td>
<td>Negative</td>
<td>0.62</td>
<td>Negative</td>
</tr>
<tr>
<td>5</td>
<td>1.5</td>
<td></td>
<td></td>
<td>Negative</td>
<td>0.62</td>
<td>Negative</td>
</tr>
</tbody>
</table>

Table 2: Inconsistent IgM Vidia® results with serological status

Table 3: Inconsistent IgM Vidia® results with avidity

Table 4: Sensitivity, specificity, VPP and VPN

CONCLUSION

In our study, the Vidia® system presented comparable results to those obtained with our installed automates, i.e. Architect® and Vidas®. In Rubella serology, the biggest challenges remain specificity in IgG and sensitivity in IgM, in order to avoid the conclusion of seropositivity when it is not or missing serocconversion during a recent infection. IgM specificity is excellent with the 3 tested methods, sparing the laboratory potential work of confirmation. IgG sensitivity is very close to 100% when the notion of « uncertain immunity » is used in the interpretation. In addition, the Vidia® system is well adapted to automation of analyses in laboratory of medium size and its use is appreciated by laboratory technicians.