

P0899

Paper Poster Session IV

Viral infection and disease

**"Evaluation of three fully automated assays for the detection of cytomegalovirus IgM and IgG: DiaSorin LIAISON®XL, Abbott Architect® and Roche Cobas 6000®"**

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*Background*

Congenital human cytomegalovirus (CMV) infection is the leading cause of congenital viral infection in developed countries, occurring in 0.3% to 2.4% of all live births. Screening for maternal CMV infection is not recommended in most countries but it is commonly performed during pregnancy. Screening for IgG allows identifying women at risk of primary infection, and therefore targeting those who specially need hygiene counselling. Testing for IgM allows identifying women that may have recent primary infection (to be confirmed by IgG avidity).

*Objective*

Our aim was to evaluate the performance of DiaSorin LIAISON®XL CMV IgG II, CMV IgM II assays in comparison with 2 other commercial assays (Abbott Architect® and Roche Cobas 6000®).

*Study design*

Several panels of serum samples were tested for CMV IgG and CMV IgM with the 3 assays: 81 sequential samples collected from 29 pregnant women during CMV primary infection (panel 1), 53 serum samples positive for CMV IgG and IgM collected from pregnant women with infection acquired more than three months before (panel 2), 81 serum samples obtained from pregnant women with past infection (CMV IgG positive and CMV IgM negative) (panel 3), and 31 serum samples from seronegative pregnant women (CMV IgG negative and CMV IgM negative) (panel 4).

*Results*

Comparative analysis between the three fully automated immunoanalyzers shows a very good correlation on clinical samples for IgG tests.

In the first 90 days following primary infection, positive IgM were respectively 92.3% with DiaSorin LIAISON®XL, 96.2% with Abbott Architect®, and 94.2% with Roche Cobas 6000®. Between 90 and 120 days following primary infection, positive IgM were respectively 76.9% with DiaSorin LIAISON®XL, 76.9% with Abbott Architect®, and 69.2% with Roche Cobas 6000®. After 120 days following primary infection, positive/equivocal IgM were respectively 81.3% with DiaSorin LIAISON®XL, 87.5% with Abbott Architect®, and 37.5% with Roche Cobas 6000®.

In the later stages of CMV infection (panel 2 and 3), The DiaSorin LIAISON®XL IgM II assay reported fewer positive results (31.3%) compared with Abbott Architect® (37.3%) but more positive results compared with Roche Cobas 6000® (20.9%). There was perfect agreement between the three assays in seronegative samples (panel 4)

*Conclusion*

The correlation between CMV IgG II and CMV IgM II tests on the DiaSorin LIAISON®XL instrument and the Abbott Architect® assay is 88.2%. This correlation is 79.7% between DiaSorin LIAISON®XL and the Roche Cobas 6000® assay. The correlation between the Abbott Architect® assay and the Roche Cobas 6000® assay is 78.5%. Overall, the lastly developed CMV IgM and IgG tests on the DiaSorin LIAISON®XL instrument are suitable for clinical use.