EV0122
ePoster Viewing
Diagnostic virology (other than hepatitis & HIV)

Clinical evaluation of automated cytomegalovirus IgG, IgM and IgG avidity assays for the LIAISON XL analyser platform

Tiziana Lazzarotto*[1], Claudia Pavia[2], Alessandra Moroni[3], Angela Chiereghin[2], Giulia Piccirilli[2], Diego Squarzoni[2], Gabriele Turello[4], Liliana Gabrielli[5]

[1]*University of Bologna; Dimes, O.U. of Clinical Microbiology, St. Orsola Malpighi University Hospital, Department of Specialised, Experimental, and Diagnostic Medicine , Bologna, Italy*

[2]*O.U. of Clinical Microbiology, Virology, St. Orsola Malpighi University Hospital, Bologna, Italy*

[3]*O.U. of Clinical Microbiology, St. Orsola Malpighi University Hospital, Bologna, Italy*

[4]*O.U. of Microbiology, Virology, St. Orsola Malpighi University Hospital, Bologna, Italy*

[5]*St Orsola-Malpighi University Hospital, Bologna, Italy*

Background: Foetal human cytomegalovirus (CMV) transmission occurs more frequently during primary infection than non-primary infection. This highlights the importance of the accurate determination of immune status during pregnancy. Maternal CMV infection is often asymptomatic, thus clinical diagnosis is unreliable and serological tests for CMV are required. Given the implications of CMV diagnosis, the assays must be thoroughly characterised with well-classified sera in order to ascertain their sensitivity and specificity and to ensure that they perform at least as well as, or better than, established routine tests on unselected samples.

The aim of this study was to evaluate the analytical performance and the clinical utility of a fully automated chemiluminescence immunoassay (CLIA) for the determination of human cytomegalovirus (CMV)-specific IgG, IgM and IgG avidity (LIAISON® XL, DiaSorin).

Material/methods: Forty-two serum samples of cord blood obtained at the end of pregnancy were reanalysed using the CLIA-IgG, IgM and IgG avidity tests. The serum samples were previously examined using Abbott Architect CMV IgG and IgM assays (chemiluminescent microparticle immunoassay-CMIA) and CMV-specific IgM immunoblot (IB) (JCM 1998, 36). Moreover, 214 sequential serum samples from 40 pregnant women with acute phase of primary CMV infection were examined.

Results: From 42 samples tested, 6 (14.3%) delivered positive results in all IgG and IgM assays. Of 36 (85.7%) samples discordant, 4 samples from uninfected CMV women were negative with all assays except CMIA-IgM test (median value 1.28 index). The remaining 32 samples from women with not active CMV infection showed IgG positive results with CMIA and CLIA assays however discordant results for CMV specific-IgM. In particular, the 32 samples were IgM-negative with IB and CLIA and positive/borderline with CMIA test (median value 1.03 index).

The 214 sequential sera had been divided into 6 groups based on the time collection, from 30 to 180 days after the beginning of primary CMV infection. The detection of CMV-specific IgM was 95-100% in all samples collected within 2 months after onset. Considering the low and moderate values of IgG-

CLIA avidity, we found 100% sensitivity in detecting a recent primary CMV infection within 90 days. The sensitivity decreased to 75% within 120 days after onset.

Conclusions: The CMV LIAISON® XL CLIA-IgM assay showed a very good specificity in samples from active and no active CMV infection compared to that one found with Architect CMIA-IgM assay (98.4% versus 12.7%). In pregnancy, the most important requirement for a CMV IgG avidity assay is to help in identifying or excluding a primary infection occurring in the previous 3 months in women presenting with a positive CMV IgM result. Therefore, the LIAISON® XL system appears useful for accurately diagnosing of CMV infection in pregnant women.