

P0498 **New developments in the diagnosis and prognosis of congenital cytomegalovirus infection**

Angela Chiereghin<sup>1</sup>, Maria Grazia Capretti<sup>2</sup>, Concetta Marsico<sup>2</sup>, Silvia Felici<sup>1</sup>, Giulia Piccirilli<sup>1</sup>, Gabriele Turello<sup>3</sup>, Liliana Gabrielli<sup>3</sup>, Tiziana Lazzarotto\*<sup>1</sup>

<sup>1</sup>*Department of Specialized, Experimental, and Diagnostic Medicine, Operative Unit of Clinical Microbiology, St. Orsola-Malpighi Polyclinic, University of Bologna, Bologna, Italy.*, <sup>2</sup>*Operative Unit of Neonatology, St. Orsola-Malpighi Polyclinic, University of Bologna, Bologna, Italy.*, <sup>3</sup>*Operative Unit of Clinical Microbiology, St. Orsola-Malpighi Polyclinic, University of Bologna, Bologna, Italy*

**Background:** Congenital cytomegalovirus (cCMV) infection is the most prevalent infection-related cause of congenital neurological disability and sensorineural hearing loss. Literature data report that CMV screening of all neonates could significantly improve the outcome of CMV-infected neonates with delayed hearing loss.

The aim of this study was to evaluate two new CMV-specific assays in order to improve the diagnosis of cCMV with a simple rapid test and identify a reliable prognostic immunological CMV-specific marker in compliance with severe neonatal CMV disease.

**Materials/methods:** The *illumigene*® CMV (Meridian Bioscience) screening test for cCMV infection provides results within 40 minutes by using saliva samples treated with lysis buffer to release nucleic acid. The QuantiFERON®-CMV (Qiagen) assay identifies CMV-specific cell-mediated immunity (CMI) evaluating IFN gamma secretion by CMV-specific CD8 positive T-cells.

**Results:** Seventy-five saliva specimens collected with dried FLOQSwabs (Copan) from 29 CMV-infected infants (ages between 1 day and 4 years) were tested with *illumigene*® CMV assay and the reference laboratory methods (extraction and Real Time PCR). Twenty-two out of 29 (76%) newborns were asymptomatic and 7 had severe symptoms. The two methods showed 100% concordance. For QuantiFERON®-CMV testing, blood samples were collected from 17 CMV-infected infants within the end of both second week and second month of life. The results were interpreted as indicated in the manufacturer instructions. Eight out of 17 (47%) infants had positive QuantiFERON®-CMV results at both evaluations and were asymptomatic. Five out of 17 (30%) infants had negative/indeterminate QuantiFERON®-CMV results at both evaluations and all were symptomatic at birth (neuroimaging abnormalities, hearing loss and disseminated disease). One out of 17 (5.9%) had a negative first QuantiFERON®-CMV result but a positive second result, and was asymptomatic. The last three newborns with both CMV-CMI negative results were asymptomatic. The results of the immunological CMV-specific test were also correlated with whole blood CMV-DNAemia.

**Conclusions:** *illumigene*® CMV test is a good and easy to use molecular assay (LAMP technology) for the cCMV infection screening. QuantiFERON®-CMV assay seems to be reliable in evaluating CMV-specific CMI in cCMV infection. The presence of CMV-specific CMI appears to correlate with asymptomatic infection at birth and during follow-up (study in progress).