

P0109

Paper Poster Session

Recent advances in diagnosis of herpes viruses

Quantification of cytomegalovirus DNA in whole blood samples using two molecular methods: plx® CMV DNA assay vs Q-CMV real-time complete kit

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Background: The aim of the study was to correlate the CMV loads measured in human EDTA whole blood clinical samples with the kPCR PLX® Cytomegalovirus (CMV) DNA Assay Using the Automated VERSANT® kPCR Molecular System by either the MiPLX Software Solution or values determined by the Q-CMV Real Time Complete Kit (ELITech Molecular Diagnostics) used in combination with the NucliSENS® easyMAG® (Biomérieux).

Material/methods: The first technology was the VERSANT® kPCR Molecular System® equipped with the new VERSANT® MiPLX Software Solution. Automated extraction, PCR set-up and amplification with the VERSANT® Sample Preparation 1.2 Reagents kit and kPCR PLX Assay Kit for CMV (Siemens Healthcare, Tarrytown, NY, USA) were used.

The second method was the automated nucleic acid extraction system NucliSens EasyMAG (bioMérieux sa Marcy l'Etoile, France) and the CMV Real time PCR systems (Q-CMV Real Time complete kit, Elitech/Nanogen, Torino, Italy) using an ABI Prism 7300 Sequence Detection System (Applied Biosystems, Monza Italy).

A dilution series of the CMV WHO Standard (NIBSC code 09/162) was tested through the kPCR PLX CMV DNA Assay (quantitation in IU/ml) and the reference method Q – CMV Real Time Complete Kit, (quantitation in copies/ml) in parallel.

Ninety EDTA whole blood clinical samples were contemporarily tested with both methods

Results: Both workflows show good correlation of their respective quantitative results (copies versus IU) with the nominal titer according to the CMV WHO Standard.

The 90 clinical samples tested were valid (no sample preparation errors occurred and all samples showed a valid Internal Control signal). By the reference assay (Q - CMV Real Time Complete Kit) 77 samples resulted positive and 13 samples negative for CMV specific DNA. Through the kPCR PLX CMV DNA Assay, 76 out of 77 samples resulted positive and 1 sample negative. This latter showed a quantitative result by the Q - CMV Real Time Complete Kit below the LOD (835 IU/ml) of the kPCR PLX CMV DNA Assay

Conclusions: In conclusion, correlation of the respective quantitative results between the kPCR PLX Cytomegalovirus (CMV) DNA Assay and the reference method (Q - CMV Real Time Complete Kit)

was good over the whole concentration range and for all sample panels tested (clinical samples as well as the 1st WHO International Standard for Human Cytomegalovirus dilution panel)