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Coefficient of variations of CMV real-time PCR assay varied from 1 to 12% for CMV DNA levels ranging between 4.0 to 1.3 log copies/ml. Comparative studies using 179 routine samples showed a concordance of 89%; 18 samples positive by CMV real-time PCR only and 2 samples positive by US Cobas. Discrepancies were only observed for samples with less than 300 copies/ml. The two assays showed high correlation ($R=0.93$), and on average values obtained by CMV real-time PCR were 0.4 log higher than those of US Cobas. Successive samples of transplanted patients with evidence of CMV infection or reactivation revealed that CMV real-time PCR assay was positive earlier and for longer period of time after treatment initiation.

Conclusion: Both assays had similar analytical performances, however the CMV real-time PCR assay has the advantages of automated extraction and higher dynamic range. On clinical samples there is a clear trend for a higher sensitivity of the CMV real-time PCR assay.

Exhibitors Symposium

S4 The innovative *qiasymphony* system from Qiagen takes ease of use to a new level

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Efficient purification of nucleic acids is critical for reliable results in downstream analyses. To address these needs, we are developing an innovative, modular system for medium-throughput sample prep and assay setup. The aim of this work is to provide an initial evaluation of the performance characteristics of the new *QIASymphony* sample prep module for fully automated purification of pathogen nucleic acids from a range of samples.

The *QIASymphony* sample prep module takes ease of use to a new level and can be operated by anyone – from the novice to the expert. Using proven magnetic-particle technology, a wide range of primary or secondary samples with input volumes up to 1 ml can be processed. You can perform all your molecular biology applications with one hardware configuration. Sample prep is even more economical since all your automated applications can be covered with just a few kits.

High process safety is assured through automated bar code reading of samples and reagents, and a fully automated load check helps to prevent human error. For increased convenience and flexibility, the system allows in-process sample loading, enabling immediate processing of urgent samples.

The *QIASymphony* system will be available in 2007. The *QIASymphony* system is under development and planned for general laboratory use. No claim or representation is intended for its use to provide information for the diagnosis, prevention, or treatment of a disease.

S5 Performance evaluation of real-time PCR based assays for the detection and quantitation of hepatitis B virus DNA

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Viral load determination for hepatitis B virus (HBV) is an essential marker for introducing and monitoring efficient therapy.

artus HBV PCR Kits are real-time PCR based assays specifically developed for the use with the LightCycler® (Roche), the Rotor-Gene 3000 (Corbett Research), and the ABI Prism® Instruments (Applied Biosystems). The goal of this work was to evaluate the performance of *artus* HBV PCR Kits in combination with highly efficient viral DNA isolation systems: the silica membrane based QIAamp DSP Virus Kit and automated, magnetic-particle technology based BioRobot® Workstations (QIAGEN).

Serial dilutions of plasma samples spiked with the HBV DNA 1st International Standard (WHO 97/746) were extracted using the QIAamp DSP Virus Kit and different BioRobot Workstations (QIAGEN). For the determination of the viral load the eluates were analyzed using *artus* HBV PCR Kits for the LightCycler® (Roche), the Rotor-Gene 3000 (Corbett Research) and the ABI Prism Instruments (Applied Biosystems).

Clinical sensitivity and specificity were evaluated and quantitative results were correlated by analyzing clinical samples using the *artus* HBV Kits in comparison with a reference method.

The specificity of the *artus* HBV assays has been proven by testing the HBV Genotype Panel (Teragenix), in-house genotyped clinical samples, precore mutation (Teragenix) and seroconversion panels (Boston Biomedica Inc.).

All viral DNA isolation systems showed highly sensitive and reliable results in combination with *artus* HBV PCR Kits for detection and quantitation of HBV. Quantitative results correlated strongly with a diagnostic reference method and all members of the HBV genotype panel were detected with comparable sensitivity.

The combination of sample preparation using the QIAamp DSP Virus Kit or BioRobot® Workstations (QIAGEN) and *artus* HBV real-time PCR assays enables sensitive and highly reliable results for the detection and quantitation of HBV.

S6 New sensations in molecular diagnostics – NucliSENS easyMAG extraction platform and NucliSENS EasyQ assays

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bioMérieux, through its NucliSENS range, offers a complete molecular diagnostic platform for extraction, amplification and real-time detection. This presentation will explain the proprietary core technologies as well as highlight some key products from the NucliSENS range.

NucliSENS extraction is based on BOOM® technology, which is recognized as the Gold Standard in nucleic acid isolation. In the new platforms the technology has been further enhanced by the introduction of magnetic silica particles. Two systems are available for magnetic extraction, i.e. NucliSENS easyMAG, the automated platform and NucliSENS miniMAG, a more manual system ideally suited for lower throughput labs.

NucliSENS amplification and detection is based on real-time NASBA® technology, which enables fast and accurate amplification and real-time detection using molecular beacons. This specific, isothermal method of nucleic acid amplification can be used for the amplification of RNA and DNA and is carried out on the NucliSENS EasyQ Analyzer.

bioMérieux is at the forefront of offering more sensitive molecular-based tests to respond to this major public health concern. An example is NucliSENS EasyQ HIV-1 v1.2, an established HIV-1 viral load assay that recently has been combined with the NucliSENS easyMAG for maximum user convenience. Furthermore assays have been developed in the range of lower respiratory tract infections (LRTI), like NucliSENS EasyQ RSV A+B, NucliSENS EasyQ hMPV, NucliSENS EasyQ SARS-CoV, NucliSENS EasyQ Influenza H5 & N1, and CNS infections like NucliSENS EasyQ Enterovirus and NucliSENS EasyQ HSV 1/2. Other assays that will complement those panels are under development.

S7 Bayer Molecular: viral load testing today and tomorrow

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Viral load testing is an important component of patient management for those with HIV or hepatitis infection. Bayer HealthCare offers comprehensive viral testing solutions including VERSANT® HIV-1, HCV, and HBV viral load assays. The VERSANT™ 440 Molecular System will perform existing bDNA assays with walkaway automation providing greater laboratory efficiency. The first new assay for this system, an increased sensitivity HCV test, is in development.