

This **annual newsletter** highlights advances in the cell culture industry and new offerings from **ViroMed Laboratories**, a LabCorp Center of Excellence.

ViroMed to Present Posters at Clinical Virology Symposium

ViroMed Laboratories' scientists conduct research throughout the year to develop innovative technology applications. ViroMed will present the two posters described below at the 27th Annual Clinical Virology Symposium and Annual Meeting of the Pan American Society for Clinical Virology in **Daytona Beach, FL, May 8-11, 2011**.

Performance Characteristics of a MultiCode-RTx® PCR Assay for the Quantitative Detection of Parvovirus B19 DNA in Serum and Plasma Samples

Kalpna Ramachandran, Bryndon Lembke, and Charles P. Cartwright
ViroMed (LabCorp) Laboratories, Minnetonka, MN

Parvovirus B19 causes a variety of diseases in humans, including erythema infectiosum, chronic anemia and fetal hydrops. Detection and quantitative monitoring of Parvovirus B19 viremia is a potentially valuable tool both for diagnosis of acute infection, and for monitoring viral activity in chronically infected, immunosuppressed, individuals. We report here on the performance characteristics of a quantitative PCR assay for Parvovirus (qParvo-PCR) that utilizes MultiCode-RTx® technology (EraGen Biosciences, Madison, WI) for detecting PCR products in real-time. One of the advantages of MultiCode-RTx® is that, since tagged-primers rather than probes are used for amplicon detection, amplification efficiency is the sole variable influencing the kinetics of signal generation resulting in improved precision of target quantitation. The qParvo-PCR assay described here enables multiplexed detection of Parvovirus B19 and an extractable internal control target. Quantitation is accomplished via interpolation of results into externally-generated, lot specific, calibration curves. We have established the analytical performance metrics of the qParvo-PCR assay, including the specimen-type specific lower limits of quantitation (LLOQ) and detection (LOD), and delineated the sample storage requirements, reproducibility, specificity and internal control performance of this novel assay. The results of these experiments indicate that this assay is capable of highly reproducible quantitation of Parvovirus DNA in serum and plasma over a range of at least 5 logs.

Validation of Alternate Sample Collection Devices for Testing Genital Samples in the MultiCode-RTx® HSV PCR Assay

Bryndon Lembke and Charles P. Cartwright
ViroMed (LabCorp) Laboratories, Minnetonka, MN

The purpose of this study was to validate the suitability of an expanded array of specimen transport media, namely, APTIMA® (GenProbe Inc.), ESwab (COPAN Diagnostics Inc.), ThinPrep® (Hologic Inc.), and SurePath™ (Becton Dickinson Inc.) for use in the detection of Herpes Simplex Virus (HSV) DNA using a previously validated real-time PCR assay. The following four parameters were assessed: 1) Confirmation of substantial equivalence of the limit of detection (LOD) for the novel sample types with the currently validated sample type (Universal Transport Media; UTM). 2) Generation of clinical validation data supporting the acceptability and comparability of APTIMA, ESwab, ThinPrep and SurePath for use in the MultiCode-RTx (EraGen Biosciences Inc.) HSV-RTx PCR assay (VML-HSV-RTx). 3) Determination of specimen stability (nucleic acid integrity) at relevant storage temperatures and times for APTIMA, ESwabs, ThinPrep and SurePath collection devices. 4) Comparability of assay performance between the current user-developed MultiCode-RTx HSV assay, MultiCode-RTx using in-vitro diagnostic (IVD) cleared reagents on an alternate instrument platform, and the IVD-cleared MultiCode-RTx assay.

The results of these experiments indicate the analytical LOD values for both HSV-1 and HSV-2 were comparable amongst the sample types evaluated and substantially equivalent to the currently claimed value for UTM. Positive and negative concordance, assay accuracy and stability were acceptable for all sample types. Crossover experiments demonstrated that comparable assay performance to that obtained using the VML-HSV-RTx version of the assay could be expected using the IVD cleared MultiCode-RTx kit with either the cleared instrument (LightCycler v1.2) and IVD data reduction software, or the RotorGene6000 and the RUO data reduction software.

Cell Culture Product Client Survey

ViroMed will be sending out its bi-annual client survey in 2011. The survey will measure client satisfaction in areas such as product quality and client service. This year we are going electronic. In May, our Web-based survey will be delivered to your e-mail address that is on file with ViroMed. Please contact ViroMed Account Management at ViroMed_AcctMgmt@LabCorp.com to verify, add, or change your account's e-mail address.

We appreciate your taking the time to provide feedback.

New Molecular Tests

Two new tests have been added to ViroMed's molecular test menu:

HIV-1 RNA Qualitative 139350

ViroMed began offering the FDA approved APTIMA® HIV-1 RNA Qualitative Assay on December 14, 2010. This assay is an in vitro nucleic acid assay system for the detection of human immunodeficiency virus (HIV-1) in human plasma. It is intended for use as an aid in the diagnosis of HIV-1 infection, including acute or primary infection. This test can detect infection with HIV-1 earlier than HIV antibody tests and is comparable to FDA-approved viral load assays in sensitivity.¹ This is the first test approved for the detection of HIV-1 RNA to help diagnose HIV-1 infection. It also has important implications for medical diagnostic use, because it could be a potential alternative to the traditional Western blot test now used for confirmation of HIV-1 infection when screening tests for HIV-1 antibodies are positive. In some instances, the Western blot can be difficult to interpret and may not always provide a conclusive result. In such cases, the APTIMA test may be helpful in HIV-1 diagnosis.¹

HHV-6 Quantitation DNA PCR 139310

ViroMed now offers both a qualitative and a quantitative assay for Human Herpesvirus 6 (HHV-6). The new quantitative assay detects and quantitates DNA in plasma and has a linear range of 100 to 1 million copies per mL. This test may be used in tracking the course of infection and monitoring response to treatment, as well as the management of cytomegalovirus (CMV) infections.

References

¹ US Food and Drug Administration. Approval of HIV-1 RNA qualitative assay for diagnostic use. Available at: <http://www.fda.gov/ForConsumers/ByAudience/ForPatientAdvocates/HIVandAIDSActivities/ucm124430.htm>. Accessed March 22, 2011.

Contact Information

For assistance with product and sales information or for any cell culture product questions or concerns, please contact ViroMed's Account Management team. They can be reached at **800-582-0077** or via e-mail at ViroMed_AcctMgmt@LabCorp.com. Please have your account number available.



ViroMed
Laboratories
A LabCorp Company

