IRL INFORMS...newsletter

Volume 3, Issue 1

INTEGRATED REGIONAL LABORATORIES IRL

VIRAL LOADS—PCR FOR HIV

Integrated Regional Laboratories now tests all HIV viral load and HCV viral load specimens with FDA-approved, real time PCR technology manufactured by Roche Diagnostics. This new testing provides improved instrument reliability and better result turnaround time, while providing enhanced sensitivity and a broad dynamic range for both HIV and HCV viral load results.

HIV viral load

The Roche COBAS Ampliprep/TaqMan HIV-1 real time PCR viral load assay has a dynamic range between 48 copies/ml to 10,000,000 copies/ml. We recently conducted a comprehensive validation study of the Roche Ampliprep RT-PCR HIV-1 viral load test using 131 actual patient samples previously tested by bDNA or by Roche. We found excellent correlation with other viral load testing methodologies with an average log difference of 0.22 $\log^{10}$. This difference is well within the current Department of Health and Human Services (DHHS) guidelines for managing patients with HIV-1 infection. You can find these guidelines at website: http://www.aidsinfo.nih.gov. The DHHS guidelines state that: "A minimally significant change in plasma viremia is considered to be a 3-fold or 0.5 $\log^{10}$ increase or decrease." You will not need to re-baseline patients previously tested by bDNA because there is a high correlation between the COBAS Ampliprep TaqMan HIV-1 test and other viral load testing methodologies. **The HIV-1 viral load Test code is 49529 and the CPT code is 87536.**

HCV viral load

The Roche COBAS Ampliprep TaqMan HCV real time PCR viral load assay offers a wide linear dynamic range of 43 IU/ml to 69 million IU/ml. Results are reported in $\log^{10}$ IU/mL and in International Units per ml. We recently performed a comprehensive validation study using 67 actual patient samples to compare results with those previously obtained by bDNA methodology and demonstrated excellent correlation with the HCV real time PCR viral load. **The HCV viral load Test code is 49530 and the CPT code is 87522.**

Important specimen collection requirements!

For HIV and HCV viral loads, please submit **2 PPT tubes** or ensure that one tube is **completely filled**. PPT tubes should be stored at room temperature prior to collection. After collection gently invert the tube 10 times and **centrifuge for 20 minutes within 2 hours of collection. DO NOT refrigerate or freeze the PPT tube after separation/centrifugation.** Transport the PPT tube to our laboratory within 24 hrs of collection **at room temperature.**

If sample will be in transit >24 hrs, the plasma must be aliquoted and sent to our laboratory frozen (aliquot plasma at room temperature to a properly labeled transfer tube and then freeze the specimen prior to transporting to IRL).

If you have any questions about this information please contact our Customer Service Department at 954-777-0018.

References:

Fully automated quantification of human immunodeficiency virus (HIV) type 1 RNA in human plasma by the COBAS AmpliPrep/COBAS TaqMan system. Schumacher W, Frick E, Kauselmann M, Maier-Hoyle V, van der Vliet R, Babiel R. J Clin Virol. 2007 38(4):304-312.

Fully automated quantification of hepatitis C virus (HCV) RNA in human plasma and human serum by the COBAS AmpliPrep/COBAS TaqMan system. Sizmann D, Boeck C, Boelter J, Fischer D, Miethke M, Nicolaus S, Zadak M, Babiel R. J Clin Virol. 2007 38(4):326-33.

It's about time.

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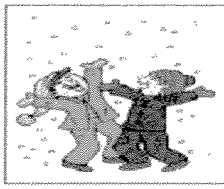

JANUARY is National Thyroid Awareness Month
FEBRUARY 14th is National Donor Day
MARCH 7th—13th is National Patient Safety Awareness Week

HIV-1/HIV-2 Plus O, EIA

HIV-1 was thought to be the sole causative agent of AIDS until 1986, when HIV-2 was isolated and also reported to cause AIDS. Since the initial discovery, although found primarily in West Africa, hundreds of HIV-2 infections have been documented worldwide. There have been more than 80 cases of infection reported in the United States. HIV-1 group O infection is endemic in west central Africa (Cameroon, Gabon and Equatorial Guinea). Patients infected with group O isolates have been identified in other geographical regions such as Belgium, France, Germany, Spain and the United States.

IRL is now offering HIV screening for HIV 1, HIV 2 and group O. Human immunodeficiency virus (HIV) strains are divided into two distinct types: HIV Type 1 (HIV-1) and HIV-2. Genetic analysis of HIV-1 isolates indicate that they are separated into 3 groups: group M (for major), including at least 10 subtypes (A through J), group O (for outlier) and group N (for non-M, non-O), The HIV-2 strains have been classified into at least five subtypes (A through E).

Both HIV-1 and HIV-2 viruses have similar morphology and lymphotropism and the modes of transmission appear to be identical. Both viruses exhibit about 60% homology in conserved genes and serologic studies have shown that the core proteins display frequent cross-reactivity.

IRL is currently performing HIV 1/2/O testing using the GS HIV-1/HIV-2 Plus O EIA kit from Bio-Rad Laboratories. This EIA kit incorporates highly conserved recombinant and synthetic peptide sequences representing HIV-1 (groups M and O) and HIV-2 with improved sensitivity and specificity for detection of the antibodies to HIV-1 and HIV-2.

Reactive specimens may contain antibodies to either HIV-1 or HIV-2. Additional , more specific or supplemental tests for antibodies to both HIV-1 and HIV-2 such as Western Blot or immunofluorescence must be performed to verify the presence of antibodies to HIV-1 or HIV-2. These tests will be reflexed as a result of reactive screening tests.

References:

Isolation of a new human retrovirus from West African patients with AIDS. Clavel F,Guetard D,Brun-Vezinet F: Science 233:343-346, 1986.

Package Insert, GS HIV-1/HIV-2 Plus O EIA, Bio-Rad Laboratories, 2008

THE USE OF GLASS COLLECTION DEVICES

Integrated Regional Laboratories does not accept samples submitted in glass collection devices. Glass tubes pose a serious and avoidable risk of blood-borne pathogen transmission to employees. Glass blood-filled tubes sometimes break during transport. Glass tubes typically fracture near the worker's fingers where force is applied when capping and recapping specimens and can cause lacerations and introduce blood directly into the wound. The volume of blood to which the employee is exposed is many times greater than that from a single needle stick exposure. Additionally, the use of glass tubes in centrifugation devices causes a significant blood borne pathogen exposure risk should the glass tubes fracture. IRL will work with clients to replace glass tubes with allowable plastic tubes thereby reducing the risk of blood borne pathogen exposure not only to IRL employees but to client employees as well.

If you have any questions or require further assistance, please call our Client Services department.

DID YOU KNOW?

Copies of our State license, Federal and CAP certifications can be found on our website: www.irlfl.com
Just click on the link, "LICENSES/CERTIFICATIONS" on the left navigation bar

24/7 CUSTOMER SERVICE SUPPORT

The Internal Customer Services department's has expanded hours of operations to provide enhanced service to our customers. Our customer service representatives will provide you with personalized service, answering your questions and ensuring a seamless working relationship. The department has transitioned to a 24/5 environment Sunday through Thursday nights, with plans to expand to a complete 24/7 environment in the near future. Understanding the needs of our customers, we measure and maintain a hold time of less than 20 seconds on average to reach a customer service representative.

ICS representatives can provide our customers with the following support services:

- STAT phlebotomy requests.
- Test code and specimen inquiries.
- Test results and test TAT.
- Additional test requests (test add ons).
- Critical results notifications.
- Problem specimen resolution.

Additional support is available for IT and technical inquiries as well. To reach an Internal Customer Service representative, please call 954-777-0018.