



## CONSOLIDATED LABORATORY SERVICES

"Continued Commitment to Quality and Service"

# Technical Bulletin

January 2011

### New 4<sup>th</sup> Generation HIV Testing now available

Effective January 2011, Consolidated Laboratory Services is pleased to announce the switch to a new HIV screening test. We have chosen to implement the Abbott Diagnostic HIV Antigen/Antibody "Combo" test.

This new "4<sup>th</sup> generation assay" simultaneously detects both antigen (p24 antigen from HIV 1) as well as antibodies to the Human Immunodeficiency Virus. The assay is specific for the detection of the HIV-1 p24 antigen as well as antibodies to HIV-1 groups M and O and antibodies to HIV-2. The median detection time is approximately 7 days earlier (range 0-20 days).

The HIV Ag/Ab Combo assay can be useful in detecting earlier, acute phase infection with HIV-1, **and prior to the emergence of antibodies. This effectively reduces the 'window' period (the time after initial infection, before the presence of detectable antibodies)** with the HIV Combo test when compared to current 3<sup>rd</sup> generation enzyme immunoassay antibody tests because of the HIV Combo test's ability to detect circulating HIV-1 p24 antigen.

In the case of the new 4<sup>th</sup> generation Combo assay, a positive immunoassay with a negative Western Blot would suggest:

- i) Early acute infection with HIV and positivity as a result of a circulating HIV p24 antigen, prior to antibody seroconversion, OR
- ii) A false positive reaction OR
- iii) An infection with an unusual HIV type.

Should the latter event occur, clinical correlation is advised. Specimens will be sent for HIV p24 antigen qualitative testing and neutralization (if positive). Testing will be performed by Specialty Laboratories.

### Signatures on Requisitions for Clinical Diagnostic Laboratory Tests

Reprinted from CMS Website <http://www.cms.gov/ClinicalLabFeeSched/>

"In the November 29, 2010 Medicare Physician Fee Schedule final rule, the Centers for Medicare and Medicaid Services (CMS) finalized its proposed policy to require a physician's or qualified non-physician practitioner's (NPP) signature on requisitions for clinical diagnostic laboratory tests paid under the clinical laboratory fee schedule effective January 1, 2011. A requisition is the actual paperwork, such as a form, which is provided to a clinical diagnostic laboratory that identifies the test or tests to be performed for a patient.

Although many physicians, NPPs, and clinical diagnostic laboratories may be aware of, and are able to comply with, this policy, CMS is concerned that some physicians, NPPs, and clinical diagnostic laboratories are not aware of, or do not understand, this policy. As such, CMS will focus in the first calendar quarter of 2011 on developing educational and outreach materials to educate those affected by this policy. As they become available, we will post this information on our website and use the other channels we have to communicate with providers to ensure this information is widely distributed. Once our first quarter of 2011 educational campaign is fully underway, CMS will expect requisitions to be signed." **Consolidated Laboratory Services will provide additional information to offices regarding this requirement as soon as it becomes available.**



See other side



## CONSOLIDATED LABORATORY SERVICES

"Continued Commitment to Quality and Service"

# Technical Bulletin

January 2011

### Changes to Cystic Fibrosis Testing

On December 13, 2010, *Consolidated Laboratory Services* began offering a new Cystic Fibrosis (CF) screen. This new test, Cystic Fibrosis Mutation Analysis, will replace the previous test shown in our Reference Manual as Cystic Fibrosis Carrier.

These changes were made after exhaustive studies conducted by our referral laboratory, *Specialty Laboratories*. The study, believed to be the largest on an ethnically diverse American population, included analysis of more than three million de-identified test results over an eight-year period ending in April 2010.

The new panel detects the 23 Cystic Fibrosis mutations recommended by the American College of Medical Genetics (ACMG) and the American College of Obstetricians and Gynecologists (ACOG). The assay will identify approximately 88% of CF mutations in the Caucasian population, 94% in the Ashkenazi Jewish population, 64% in the African-American population, 72% in the Hispanic-American population, and 49% in the Asian-American population. Separate tests are available for patients without and with a family history of CF.

New forms will be distributed to your office as quickly as possible. Until your new forms arrive, you may continue to use the older version. The new 23 mutation analysis will be substituted for the previous 70 mutation offering.

### Changes to Critical Value and Specimen Integrity Notification

Critical values for several tests will now be called to physicians from 8:00am-5:00pm daily instead of 24 hours a day. This change was implemented after receiving feedback from physicians who did not feel that calls later in the evening were warranted by the specific analyte.

A second change is being implemented to provide your practitioners with a more thorough portrayal of potential specimen integrity issues. Testing samples within a specific timeframe, testing from properly spun test tubes, and inclusion of the date/time of collection on the requisition are all needed to ensure specimen integrity.

Starting December 20<sup>th</sup>, results from samples with possible integrity issues will be notated on the patient report.

- Samples received in our lab with a date/time of collection greater than 24 hours of receipt will have the following message appended to the report: **"Specimen collection date and time exceeds 24 hrs of receipt date and time; therefore the accuracy of the results may be questionable. Any critical values associated with this specimen will be called between the hours of 8 am to 5 pm. Clinical correlation is necessary for interpretation."**
- Samples received in tubes that were unspun or with visible cellular contamination will have the following message appended to the report: **"Specimen received unspun or showed poor separation from red cells; therefore the accuracy of the results may be questionable. Any critical values associated with this specimen will be called between the hours of 8 am to 5 pm. Clinical correlation is necessary for interpretation."**
- Samples without any date or time of collection will have the following message appended to the report: **"Specimen collection date/time is unknown; specimen integrity cannot be assured. Date of receipt used as default."**



See other side