

May 10, 2013

**\*\* ENZO CLINICAL LABS INTRODUCES \*\***

**FOURTH GENERATION HIV TESTING & NEW DIAGNOSTIC ALGORITHMS FOR  
DETECTING HIV INFECTION**

Effective Monday, May 13, 2013, Enzo Clinical Labs is moving HIV screening to a 4<sup>th</sup> generation assay. This FDA approved Bio-Rad assay includes testing for both antibody to HIV 1 and 2 infections, along with the p24 HIV antigen and narrows the window of detection between infection and seroconversion by several weeks. The assay is also more sensitive than current 3<sup>rd</sup> generation testing for antibody alone, and allows detection of HIV infected persons earlier when they are most infectious. The CDC has proposed using a 4<sup>th</sup> generation HIV screening algorithm coupled with more sensitive discriminating tests and nucleic acid amplification testing when needed. The new approach allows for more effective diagnosis than the older algorithm that includes Western Blot confirmatory testing. Western Blot testing does not detect infection in the approximately 40 day period when measurable antibody is not present.

Initially ECL will continue to use Western Blot confirmatory testing, but we will soon offer the newly FDA approved discriminatory testing, Bio-Rad's Multi-Spot assay, which will allow us to fully follow the new CDC recommended algorithm.

If the 4<sup>th</sup> generation HIV screen is positive, a preliminary report will be issued but will be qualified to indicate that confirmatory testing by Western Blot is pending.

**TEST INFORMATION**

<b>Test Name:</b>	HIV Ag/Ab Screen
<b>Test Code:</b>	1409
<b>Specimen Requirements:</b>	Dedicated SST Tube
<b>Test Schedule:</b>	Monday-Friday

*Please contact your Enzo Sales Representative, go online to [www.enzoclinicallabs.com](http://www.enzoclinicallabs.com) or call 800.522.5052 for more information.*