



LABORATORY UPDATE

November 10th, 2017

ENZO CLINICAL LABS INTRODUCES **FIFTH GENERATION HIV TESTING**

Dear Physician(s) and Staff,

Effective Monday November 13, 2017, Enzo Clinical Labs will offer the 5th generation HIV Ag/Ab screening assay. This FDA approved multiplex flow immunoassay simultaneously tests for HIV 1 p24 Antigen, HIV 1 Antibody (groups M & O) and HIV 2 Antibody specifically identifying which individual HIV-1 or HIV-2 marker is positive. This assay detects acute infections earlier, differentiates recent infections from established infections, and has the best analytical sensitivity for HIV testing. The 5th generation HIV screening test, coupled with more sensitive discriminating tests and nucleic acid amplification testing follows the CDC's recommended testing algorithm. This new approach allows for more effective diagnosis than 4th generation assays.

If the 5th generation HIV screening assay is positive, supplemental testing by Bio-Rad's Geenius™ assay will be performed, followed by HIV-1 RNA nucleic acid amplification testing if indicated.

TEST INFORMATION	
TEST NAME:	HIV AG/Ab Screen
TEST CODE:	1409
SPECIMEN REQUIREMENTS:	Dedicated SST
TESTING SCHEDULE:	Monday-Friday (excluding holidays)

We appreciate the continued opportunity to serve you and your patients and welcome any questions or concerns you may have. You can reach us at 631-755-5500 or talk to your Enzo Clinical Labs Sales and/or Service Representative for more information.

Sincerely,

Dieter Schapfel, MD
Medical Director

5th Generation HIV 1/2 Ag/Ab Result Guidance

HIV Ag-Ab* Result	HIV-1 Ab Result	HIV-1 Ag Result	HIV-2 Ab Result	Notes
Reactive	Non-Reactive	Non-Reactive	Reactive	Suggests HIV-2 established infection
Reactive	Reactive	<i>Not Reportable due to high HIV Ab level</i>	Non-Reactive	Suggests HIV-1 established infection. HIV-1 Ag level cannot be accurately reported
Reactive	Reactive, Undifferentiated	Non-Reactive	Reactive, Undifferentiated	Suggests HIV-1 and/or HIV-2 established infection. Differentiation cannot be accurately reported
Reactive	Reactive	Reactive	Non-Reactive	Suggests HIV-1 acute infection and seroconverting to HIV-1 established infection
Reactive	Non-Reactive	Reactive	Non-Reactive	Suggests HIV-1 acute (primary) infection
Non-Reactive	Non-Reactive	Non-Reactive	Non-Reactive	No infection (most common expected result)
Reactive	Non-Reactive	<i>Not Reportable due to high HIV Ab level</i>	Reactive	Suggests HIV-2 established infection. HIV-1 Ag level cannot be accurately reported
Reactive	Reactive	Non-Reactive	Non-Reactive	Suggests HIV-1 established infection (most common reactive result)
Reactive	Reactive, Undifferentiated	Reactive	Reactive, Undifferentiated	Suggests HIV-1 acute infection and seroconverting to HIV-1 established infection and/or HIV-2 established infection. Differentiation cannot be accurately reported. Highly unlikely and probably biological false positive
Reactive	Non-Reactive	Reactive	Reactive	Suggests HIV-1 acute infection and HIV-2 established infection. Highly unlikely

Source: Bio-Rad Laboratories, 4000 Alfred Nobel Dr. Hercules, CA 94547

***The HIV Ag-Ab column is considered the “overall” result (i.e., assay interpretation); it looks at the three individual results to make a determination.**