Technical Bulletin

HIV Antigen/Antibody Screen Test Provides Analyte-Specific Results

TO: Medical Staff and Clients

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DATE: July 8, 2022

SUBJECT: **New HIV screen provides antigen and antibody results, but still requires reflex confirmation**

Effective July 12, 2022, Diagnostic Laboratory Services, Inc. (DLS) will switch to an HIV screen test that, in addition to an overall result, will also provide results for HIV-1 antigen, HIV-1 antibody, and HIV-2 antibody. Although these analytes are reported, it is not FDA labeled as a differentiation test (BioPlex® 2200 HIV Ag-Ab Assay), so cannot be used as the second step in the Centers for Disease Control and Prevention (CDC) algorithm (CDC HIV testing algorithm). It still requires reflex confirmation by HIV-1/HIV-2 antibody differentiation assay.

The new test code is **7760**, and on the effective date, the old test code (5688) will automatically switch to the new code. This is a reflex test code, which means if the screen test is positive, the next test (HIV-1/HIV-2 antibody differentiation assay) will be performed.

Rarely (0.14%-0.23%), this second test will result as **negative** for HIV-1 and HIV-2 antibody, **or is indeterminate**, two explanations are most likely:

1. Usually this is a false-positive initial test, especially in low risk patients. Whenever an ultra-sensitive test such as this is used in a very low risk population (e.g., new OB in which the prevalence of disease approaches zero), statistically speaking, the positive is probably false.

2. Infrequently, this is an early acute infection in which the test detects antigen but there has not been adequate time for antibody formation.

To best resolve the discrepancy between the first two tests, the next test in the CDC algorithm is HIV-1 Nucleic Acid Test (NAT). An HIV-2 NAT is not performed because HIV-2 is rare in the U.S. Most of the time this test is negative, which confirms the false-positive initial test result.

The HIV-1 antigen is NOT a reliable indicator of viral load. For example, in high-antibody-titer specimens, HIV-1 antigen becomes unreliable, and may not be reported.

This change is in response to acute supply disruptions. It may or may not become permanent.

Please refer any questions to Jantzen Lim, Manager - DLS Core Laboratory at 808-589-5265 or DLS Client Services at 808-589-5101.