FILE DEFINITION TEST CHANGE

Notification Date: March 27, 2023 Effective Date: May 9, 2023

HIV-1 and HIV-2 Antigen and Antibody Diagnostic Evaluation, Plasma

Test ID: HIVDX

Explanation: On the effective date, the testing algorithm will be updated to facilitate resolution of HIV antigen/antibody discrepancies with qualitative molecular testing (including HIV-2), and quantitative molecular testing of specimens confirmed positive for HIV-1 antibodies.

Current Algorithm

This test begins with HIV-1/-2 antigen and antibody screen by chemiluminescence immunoassay. If the screen result is reactive, then HIV-1/-2 antibody confirmation/differentiation test (**HVDIP**) by immunochromatographic method is performed at an additional charge.

If the HIV-1/-2 antibody confirmation/differentiation test (**HVDIP**) is negative for both HIV-1 antibody and HIV-2 antibody, or indeterminate/negative for HIV-1/-2 antibody, or indeterminate/indeterminate for HIV-1/HIV-2 antibody, then HIV-1 RNA detection and quantification (**HIVQN**) is performed at an additional charge.

New Algorithm

This test begins with HIV-1/-2 antigen and antibody (Ab) screen by chemiluminescence immunoassay. If the screen result is reactive, then HIV-1/-2 antibody confirmation/differentiation test (HVDIP) by immunochromatographic method is performed at an additional charge.

If the following result types are obtained from the HIV-1/-2 confirmation/differentiation test (**HVDIP**), HIV-1/HIV-2 RNA detection (**HIP12**) will be performed at an additional charge:

- Negative for both HIV-1 Ab and HIV-2 Ab
- Indeterminate for HIV-1 Ab but negative for HIV-2 Ab
- Negative for HIV-1 Ab but indeterminate for HIV-2 Ab
- Indeterminate for both HIV-1 Ab and HIV-2 Ab
- Positive for both HIV-1 Ab and HIV-2 Ab

If the following result types are obtained from the HIV-1/-2 confirmation/differentiation (**HVDIP**), HIV-1 RNA detection and quantification (**HIVQN**) will be performed at an additional charge:

- Positive for HIV-1 Ab and negative for HIV-2 Ab
- Positive for HIV-1 Ab and indeterminate for HIV-2 Ab

Current Reflex Tests

HVDIP - HIV Ab Confirm / Differentiation, P

HIVQN - HIV-1 RNA Detect/Quant, P

New Reflex Tests

HVDIP - HIV Ab Confirm / Differentiation, P

HIP12 - HIV-1/HIV-2 RNA Detect, P (new test code)

HIVQN - HIV-1 RNA Detect/Quant, P

Questions

Contact James Conn, Laboratory Resource Coordinator at 800-533-1710.