AT THE FOREFRONT
UChicago Medicine

DATE: September 14, 2022

TO: UCM Medical Staff, Housestaff, Nursing Staff, Patient Care Centers, and Outpatient Clinics

FROM: KT Jerry Yeo, PhD, DABCC, FAACC
Medical Director, Clinical Chemistry Laboratories

RE: HIV Duo Qualitative Screening Assay

Effective September 14, 2022, we will be replacing the current HIV screening assay (HIVSCR) with the Roche **Elecsys HIV Duo electrochemiluminescent assay.** The new test code will be **LABCHHIVRFL(HIVDUO).** This plasma assay (EDTA lavender-top tube) provides the simultaneous qualitative detection of and differentiation between HIV-1 p24 antigen as well as antibodies to HIV-1 (groups M & O) and HIV-2.

HIV p24 antigen can be detected in blood as early as 2-3 weeks post-infection, while anti-HIV antibodies are usually detectable approximately 4 weeks after infection. Reactive (positive screen) samples will be automatically reflexed to the Microbiology laboratory for confirmation.

The HIV results will be displayed in Epic with its components as shown in the examples below:

A) Positive Screen for p24 Antigen	B) Negative Screen for P24 Antigen and HIV Antibodies
HIV Antibodies: Non-Reactive	HIV Antibodies: Non-Reactive
HIV Antigen: Reactive	HIV Antigen: Non-Reactive
HIV Duo: Reactive	HIV Duo: Non-Reactive

*Please note that any component that showed a reactive result will cause the composite HIV Duo reading, which is a summary result of the components to be read as reactive.

This assay is intended to be used as an aid in the diagnosis of HIV-1 and/or HIV-2 infection in **subjects greater than 2 years old and in pregnant patients**. It cannot be used for screening of blood and plasma donors. Other limitations include:

- May not detect all infected individuals. A negative test does not exclude the possibility of exposure/infection as HIV antibodies and/or p24 antigen may be undetectable in some stages of infection and in some clinical situations
- HIV vaccinated person may develop antibodies to the vaccine and may or may not be infected with HIV
- Anomalous results may result due to a patient's exposure to heterophilic and human antibodies to mouse antigens, or patients receiving therapeutic/diagnostic monoclonal antibodies which can interfere with this assay.

If you have any questions, please contact me at 773-702-1318 or jyeo@bsd.uchicago.edu