ASANTE®
Rogue Regional Medical Center

TO: Asante Clinicians and Providers

FROM: Phyllis Feusahrens, Outreach Manager

DATE: February 4, 2016

SUBJECT: 4th Generation HIV-1/2 Antibody and HIV-1 Antigen Test

Effective February 10, 2016, the Asante Rogue Regional Medical Center Laboratory will be performing a new 4th Generation combination HIV-1/2 antibody and HIV-1 antigen test, replacing our current HIV antibody screen. Below are updated recommendations published by the Centers for Disease Control and Prevention (CDC), June 27, 2014.

The recommended algorithm is a sequence of tests used in combination to improve the accuracy of the laboratory diagnosis of HIV based on testing of serum specimens. The updated recommendations also include tests for HIV antigens and HIV nucleic acid because studies from populations at high risk for HIV demonstrate that antibody testing alone might miss a considerable percentage of HIV infections.

These recommendations do not include the rapid HIV-1/HIV-2 antigen/antibody combination test approved by the FDA in August 2013.

These updated recommendations for HIV testing are necessary because of:

- FDA approval of improved HIV assays that allow detection of HIV sooner after infection than previous immunoassays.
- Evidence that relying on Western blot or indirect immunofluorescence assay (IFA) for confirmation of reactive initial immunoassay results can produce false-negative or indeterminate results early in the course of HIV infection.
- Recognition that risk of HIV transmission from persons with acute and early infection is much higher than that from persons with established infections.
- Recent indications for the clinical benefits from antiretroviral treatment (ART) of all persons with HIV infection, including those with acute infection.
- Demonstration that the majority of HIV-2 infections detected by available HIV antibody immunoassays are misclassified as HIV-1 by the HIV-1 Western blot.

This report provides recommendations to laboratory personnel on the use of FDA-approved assays for the diagnosis of HIV infection in adults and children > 24 months of age. In brief, testing begins with a combination immunoassay that detects HIV-1 and HIV-2 antibodies and HIV-1 p24 antigen. All specimens reactive on this initial assay undergo supplemental testing with an immunoassay that differentiates HIV-1 from HIV-2 antibodies.

(**Continued on reverse)**

Specimens that are reactive on the initial immunoassay and nonreactive or indeterminate on the antibody differentiation assay proceed to HIV-1 nucleic acid testing for resolution.

EPIC Test Description: HIV Antigen and Antibody
Asante Laboratory Information System Test Code: HIVAA

<u>Supplemental testing order codes</u>:

HIVDI (HIV-1/2 Antibody Differentiation, Serum)
HIVUSB (HIV-1 RNA Detect/Quant, Plasma)

HIVDI will be sent to Mayo Medical Laboratories following any reactive HIV-1/2 antibody/ HIV-1 antigen result. If the HIVDI test is negative or equivocal, the patient will need to be redrawn for the HIV-1 RNA test, as the HIV-1 RNA requires an EDTA plasma sample.

The HIV-1 Western blot and HIV-1 IFA, previously recommended to make a laboratory diagnosis of HIV-1 infection, are no longer part of the recommended algorithm. Positive results from the recommended algorithm indicate the need for HIV medical care and an initial evaluation that includes additional laboratory tests (such as HIV-1 viral load, CD4+ T-lymphocyte determination, and an antiretroviral resistance assay) to confirm the presence of HIV-1 infection, to stage HIV disease, and to assist in the selection of an initial antiretroviral drug regimen. Because no diagnostic test or algorithm can be completely accurate in all cases of HIV infection, inconsistent or conflicting rest results obtained during the clinical evaluation may warrant additional testing of follow-up specimens.

Please contact Robert Stephenson, MD, 541-789-4191, Jack Montgomery, ARRMC Chemistry Technical Specialist, 541-789-4175, or Phyllis Feusahrens, Outreach Manager, 541-789-5310, if you have questions.