Draft Recommendations:
Diagnostic Laboratory Testing for HIV Infection

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4th generation HIV-1/2 immunoassay

(+)

((-)

Negative for HIV-1 and HIV-2 antibodies and p24 Ag

HIV-1/HIV-2 antibody differentiation immunoassay

HIV-1 (+) HIV-2 (-)
HIV-1 antibodies detected

HIV-1 (-) HIV-2 (+)
HIV-2 antibodies detected

HIV-1 (+) HIV-2 (+)
HIV antibodies detected*

HIV-1 (-) or indeterminate

RNA

RNA (+) RNA (-)
Acute HIV-1 infection Negative for HIV-1

*Additional testing required to rule out dual infection
1. Initiate screening with a 4th generation Ag/Ab combination immunoassay (IA)

2. Reactive (repeatedly reactive) specimens should be tested with a 2nd generation Ab IA that differentiates HIV-1 from HIV-2 antibodies.

3. Persons whose specimens are positive on the initial IA and antibody differentiation IA should be considered positive for HIV-1 or HIV-2 antibodies and initiate medical care that includes laboratory tests such as viral load, CD4, and antiretroviral resistance assays.
4. Specimens reactive on the initial IA and negative on the HIV-1/HIV-2 Ab differentiation IA should be tested for HIV-1 RNA. A reactive result indicates Acute HIV-1 infection.

5. Follow this same testing algorithm (beginning with 4th generation IA) for specimens with a previous reactive rapid HIV test result.
Alternatives

1. If 3rd gen HIV-1/2 IA as initial test: perform subsequent testing specified in the algorithm.

2. If alternative 2nd Ab test is used (e.g., WB or IFA): If negative or indeterminate, perform HIV-1 NAT; if HIV-1 NAT is negative, perform Ab IA for HIV-2

3. HIV-1 NAT as 2nd test: if positive, HIV-1 infection; if negative, perform HIV-1/HIV-2 Ab differentiation assay.
Considerations

1. **Supersede**
   - Recommendations for Use of Western Blot (1989)
   - Protocols for confirmation of reactive rapid tests (2004)

2. **Screens for both virologic and serologic markers of HIV infection**
   - Incorporates NAT to resolve discordant IA results
   - Identifies acute HIV-1 infection
   - Reduces indeterminate test results

3. **All IA-positive specimens tested for HIV-2**
Considerations

4. Emphasizes sensitivity
   - For initial testing
   - During supplemental testing

5. Rare false-positive antibody test results might occur
   - False-positive results would be discovered during subsequent laboratory testing recommended as part of initial clinical evaluation
Plan for Public Engagement during 2012 HIV Diagnostics Conference

1. Assess scientific presentations and implications for the draft testing recommendations

2. Provide specific comments and suggestions during feedback session on Friday December 14.