HIV Testing Algorithm Case

Clinical Scenario

- 35 year old male with history of asthma, who came in with the following sexual history from the past 3 months:
  - Contact 1) Reported HIV negative
  - Contact 2) Oral sex only, but gum disease present
  - Contact 3) HIV negative at time of contact in mid-February, but HIV positive by March
  - Contact 4) Gave oral sex
HIV Serologies

- November 2008 - negative HIV 1/2 EIA test
- February 27, 2009 - negative HIV rapid test
- March 10, 2009 - reactive HIV 1/2 serology
- March 10, 2009 - HIV-1 Western blot negative
  - No bands detected
  - Laboratory interpretation – No evidence for HIV infection

Laboratory Studies

- March 20, 2009: WBC 5700
  - 41% neutrophils, 47% lymphocytes, 11% monocytes
- March 27: WBC 9700
  - 15% neutrophils, 4% bands, 25% lymphocytes, 50% atypical lymphocytes, 5% monocytes
  - Platelets now 115,000 from 220,000 /cmm one week ago
- ALT 84 IU/L
- RPR nonreactive
- Urethral NAAT and anal/pharyngeal cultures negative for Chlamydia/gonorrhea
HIV-related Data

- HIV-1 RNA PCR 1.1 million copies/mL on March 20, 2009
- HIV-1 EIA and Western blot both positive from March 20.
  - P24, p40, p51, and gp160 bands present
- CD4 1470 cells/cmm on March 27, 2009

4th Generation Ag/Ab Tests

- Can detect HIV-1 during the acute stage as well as the chronic stage of infection
  - Due to the addition of p24 Antigen
- Three 4th generation Ag/Ab tests have been approved by the FDA (as of September 2013)
  - ARCHITECT HIV Ag/Ab Combo (Abbott)
  - GS HIV Ag/Ab Combo EIA (Bio-Rad)
  - Determine HIV-1/2 Ag/Ab Combo test (Alere)
- All 3 tests will detect HIV-1 p24 Ag and antibodies to HIV-1 and HIV-2
Detection of HIV by Diagnostic Tests

<table>
<thead>
<tr>
<th>Symptoms</th>
<th>p24 Antigen</th>
<th>HIV RNA</th>
<th>HIV EIA*</th>
<th>Western blot</th>
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**0 1 2 3 4 5 6 7 8 9 10**

**Weeks Since Infection**

- 4th generation – combines 3rd generation with a p24 antigen
- *3rd generation, IgM-sensitive EIA
- *2nd generation EIA
- *viral lysate EIA

After Fiebig et al, AIDS 2003; 17(13):1871-9

New HIV Diagnostic Testing Algorithm

1. **HIV-1/2 Ag/Ab combo immunoassay (4th generation)**
   - (+): Negative for HIV-1 and HIV-2 antibodies and p24 Ag*
   - (-): HIV-1/2 antibody differentiation immunoassay

2. **HIV-1/2 antibody differentiation immunoassay**
   - HIV-1 (+) HIV-2 (-): Positive for HIV-1 antibodies
     - Initiate care
   - HIV-1 (-) HIV-2 (+): Positive for HIV-2 antibodies
     - Initiate care
   - HIV-1 (+) HIV-2 (+): Positive for HIV antibodies
     - Initiate care
   - HIV-1 (-) or indeterminate HIV-2 (-): HIV-1 RNA assay

3. **HIV-1 RNA assay**
   - RNA (+): Positive for HIV-1
     - Initiate care
   - RNA (-): Negative for HIV-1
     - Initiate care

Slide courtesy of Monica Parker, PhD, Wadsworth Laboratory
Take-Home Points

1) New algorithm would have picked up this HIV seroconverter

2) New algorithm allows for the diagnosis of acute HIV infection

3) Negative result on 4th generation screen does NOT exclude the possibility of acute HIV infection