HIV Testing Update
Florida PPG
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Tampa, FL

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Testing in Florida

- Over 420,000 HIV Antibody Tests in 2011
  - Blood (150,452)
  - Rapid (226,121)
  - OraSure (43,251)
Testing – By the Numbers

- Total Tests: 420,589
  - Male: 186,626
  - Female: 229,727
  - Black: 188,823
  - Hispanic: 99,266
  - White: 116,604
  - MSM: 35,726
  - Hetero: 244,910

- 1.10% Positive
  - Male: 1.81% Positive
  - Female: 0.51% Positive
  - Black: 1.29% Positive
  - Hispanic: 1.03% Positive
  - White: 0.88% Positive
  - MSM: 5.57% Positive
  - Hetero: 0.41% Positive
The Technology
EIA (Enzyme Immunoassay)

- Looks for Antibodies or Specific Parts of Antibodies
  - An antibody specifically directed against one or more proteins or antigens on the surface of HIV
  - These assays include recombinant or synthetic peptide antigens derived from HIV groups M and O, in addition to HIV-2, as the capture antigens.
- Also included in third-generation EIAs are the abilities to detect both IgG and IgM. This capability lends greater sensitivity to early HIV antibody detection because IgM is the first immunoglobulin product of the humoral immune response, reaching detectable concentrations in the blood prior to IgG
Western Blot

- Done to confirm result of EIA
- Looks for HIV antibodies
- Less sensitive during early infection than other tests currently in use
  - Can take up to 3 months or more to confirm infection
- Results:
  - Positive
  - Negative
  - Indeterminate
Old Technology

While it is a very good test it is a step backward in technology
4th Generation

- 4th Generation IA Began in April 2012
- Abbott Diagnostics’ Architect HIV Ag/Ab Combo
- Antigen is produced (and should be detectable) before antibody
- Could yield a 10–12-day reduction in the window period
- Does not indicate whether it was antibody or antigen that was detected
- Ag/Ab Rapid Test On the Way
4th Generation Confirmatory

- Confirmatory Testing
  - IA Positive – Multispot Confirmatory

- Multispot Can Detect HIV-1 and HIV-2
- Quickly identifies Ab+ (including those WB -)
4th Generation Confirmatory

- IA positive – Multispot negative
- Conduct Nucleic Acid Amplification Test (NAAT)
  - Looks for actual virus (HIV-1 RNA)
  - Reduces window period to 1 to 2 weeks
  - Blood only
4th Generation Performance

4/16/12 – 9/16/12   n = 51,953

4th Generation Abbott HIV-1/2 Ag/Ab Combo Performance
Sensitivity = 100% (922/922)
Specificity = 99.86% (50961/51031) [PI claim 99.77% (99.62-99.88%)]

New algorithm performance;
Sensitivity = 100% (922/922)
Specificity = 99.99% (51030/51031)
PPV = 99.9% (922/923)

Two HIV-1 acute infections (algorithm defined) detected.
No HIV-2 cases detected.
OraQuick In Home Test Kit
Insti Rapid Test

- Requires 50 ul of blood
- 3-step mixing process
- Results in as little as 60 seconds
- 99.8% Sensitivity and 99.5% Specificity
Testing Expectations

- Routine opt-out testing* of patients ages 13-64 in healthcare settings
- Targeted testing programs in non-healthcare settings
- Routine, early HIV screening for all pregnant women
- Screening for other STDs, hepatitis, and tuberculosis in conjunction with HIV testing
Testing Expectations

CDC expects each funded jurisdiction to achieve the following performance standards, when the program is fully implemented:

- For targeted HIV testing in **non-healthcare** settings or venues, **achieve at least a 1.0% rate of newly identified HIV-positive tests annually for prevention and 2% for ETI**.
- At least 85% of persons who test positive for HIV receive their test results.
- At least 80% of persons who receive their HIV positive test results are linked to medical care and attend their first appointment.
- At least 75% of persons who receive their HIV positive test results are referred and linked to Partner Services.
- Have a plan to address situations in which the **yield of newly diagnosed positives is below 0.1% in healthcare settings**.
Questions?