Identification of Early HIV Infections using the Fourth Generation Abbott Architect HIV Ag/Ab Combo Chemiluminescent Microparticle Immunoassay (CIA) in San Diego County

Anna Liza M. Manlutac, PHM
Supervising Public Health Microbiologist
San Diego County Public Health Laboratory
HIV Fast Facts

- 2012: ~207,600 (undiagnosed HIV infection)
- 18% of ~1.1M HIV infected

Source: Aidsvu.org
San Diego County

- San Diego covers over 4,200 square miles
- Estimated 2011 population is 3,140,069
- 7th largest city in the US
- Shares the world’s busiest border crossing with Tijuana, Mexico
- 2007-2011: 1,819 individuals diagnosed with HIV infection
  - Overall rate of 59.4 per 100,000
  - 91% male; 9% female

Source: County of San Diego, Epidemiology & Immunization Services, Epidemiology Program
San Diego County

- Serves a relatively large population of at risk individuals
- Ranks ~22nd in the U.S. for prevalence of cases of AIDS in Metropolitan Statistical Areas.
- #3 in the state of CA for HIV or AIDS cases
- #11 for rate of AIDS cases per 100,000 in the Continental US
HIV in San Diego County
2007-2011

Source: County of San Diego, Epidemiology & Immunization Services, Epidemiology Program
HIV in San Diego County 2007-2011

Racial/Ethnic Group

<table>
<thead>
<tr>
<th>Race</th>
<th>Rate per 100,000 Population</th>
</tr>
</thead>
<tbody>
<tr>
<td>White</td>
<td>52.4</td>
</tr>
<tr>
<td>Black</td>
<td>183.0</td>
</tr>
<tr>
<td>Hispanic</td>
<td>67.8</td>
</tr>
<tr>
<td>Asian/Other</td>
<td>24.3</td>
</tr>
</tbody>
</table>

Age at Diagnosis

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Rate per 100,000 Population</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;20</td>
<td>7.3</td>
</tr>
<tr>
<td>20-29</td>
<td>127.7</td>
</tr>
<tr>
<td>30-39</td>
<td>122.8</td>
</tr>
<tr>
<td>40-49</td>
<td>91.6</td>
</tr>
<tr>
<td>50+</td>
<td>21.1</td>
</tr>
</tbody>
</table>

Source: County of San Diego, Epidemiology & Immunization Services, Epidemiology Program
HIV Testing in San Diego County

- STD/HIV Public Health Clinics
- County Detention Facilities
- County Psychiatric Hospital
- University Medical Center
- Special Projects/Surveillance Programs
HIV Testing Opportunity in SD County

In late 2010, started collaboration with our HIV, STD & Hepatitis Branch to switch from a third-generation HIV EIA (Avioq HIV-1 Microelisa system) to the newly FDA-approved fourth-generation Abbott Architect HIV Ag/Ab Combo Chemiluminescent Microparticle Immunoassay (CIA).
Viral Markers for HIV infection

Lack of Awareness → Ongoing Transmission

Awareness of Serostatus Among People with HIV and Estimates of Transmission

- ~25% Unaware of Infection
- ~75% Aware of Infection

People Living with HIV/AIDS: 1,039,000-1,185,000

- Accounting for:
- ~54% of New Infections

- ~46% of New Infections

New Sexual Infections Each Year: ~32,000

Marks, et al. AIDS 2006;20:1447-50

CDC
Acute Phase ➔ High Viral Load ➔ More New Infections

---

**ESTIMATED NUMBER OF NEW HIV INFECTIONS PER 100 PERSON-YEARS AMONG HETEROSEXUAL SERODISCORDANT COUPLES BY SERUM VIRAL LOAD OF HIV PARTNER**

- 50,000 or more copies/ml: N=26
- 10,000–49,999 copies/ml: N=15
- 3,500–9,999 copies/ml: N=13
- <3,500 copies/ml: N=2

---

12/18/2012 2012 HIV Diagnostics Conference
Early Detection of HIV Infection by 4th Gen test

166 Specimens from 17 seroconverters were tested

ARCHITECT HIV Ag/Ab Combo Assay

- **Simultaneous qualitative detection**
  - HIV p24 antigen and antibodies to HIV type 1 (M & O) and/or HIV-2 in serum and plasma

- **Intended Use**
  - Detects HIV infections including *Acute HIV Infection (AHI)*
  - Pediatric subjects as young as 2 years old
  - Pregnant Females

Source: ARCHITECT HIV Ag/Ab Assay Package insert
ARCHITECT HIV Ag/Ab Combo Assay

- **p24 antigen sensitivity**
  - As low as 18 pg/ml of p24
  - As low as 15,000 RNA copies/ml

- **Increased Specificity**
  - 99.77%

- **Excellent Workflow**
  - Fully-automated
  - Random-access
  - 29 minutes to first result
  - ~80 tests per hour

Source: ARCHITECT HIV Ag/Ab Package insert
SDPHL Experience

- **2/2011**: installation, training and verification
  - 1 PHM was sent to Dallas for Architect training
- **Validation of the Abbott Architect**
  - Test samples required:
    - 20 (R) and 20 (NR) previously tested sera
    - External controls positive for HIV-1 antibodies, HIV-2 Antibodies and HIV-1 p 24 antigen
- **Data collected:**
  - Qualitative results
  - Comparison data between current assay and the CIA
  - State results
  - Quest results
SDPHL Experience

- 3/7/2011: “GO LIVE”
- 3/9/2011 - First CIA pos, IFA pos result
- 3/15/2011 – First CIA pos, IFA neg result
- 3/17/2011 – First HIV-1 RNA result (pos)
- Testing Period: 3/7/2011 to PRESENT
HIV Testing Algorithm

ARCHITECT HIV Ag/Ab Combo Assay (14,517)

- NON-REACTIVE (14,233)
  - No Evidence of HIV Infection
  - REPORT RESULT

- INITIAL REACTIVE (284)
  - RETEST IN DUPLICATE

  - REPEAT reactive (279)
  - DID NOT REPEAT (5)

    - HIV-1 IFA (279)
      - IFA NON-REACTIVE (39)
        - SEND TO COMMERCIAL LAB
          - HIV-1 RNA (30)
            - 17 Detected
            - 13 Not Detected

        - SEND TO VRDL
          - HIV-2 (35)
            - 35 Not Detected

    - IFA REACTIVE (240)
      - REPORT RESULT
### March 2011 to November 15, 2012

<table>
<thead>
<tr>
<th>Description</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>TOTAL SAMPLES RECEIVED</td>
<td>14,559</td>
</tr>
<tr>
<td>UNSATISFACTORY SPECIMENS NOT TESTED</td>
<td>42</td>
</tr>
<tr>
<td>HIV COMBO 4(^{th}) GEN TESTED</td>
<td>14,517</td>
</tr>
<tr>
<td>HIV COMBO 4(^{th}) GEN NON-REACTIVE</td>
<td>14,238</td>
</tr>
<tr>
<td>HIV COMBO 4(^{th}) GEN REPEAT REACTIVE (RR)</td>
<td>279</td>
</tr>
<tr>
<td>HIV COMBO 4(^{th}) GEN REPEAT REACTIVE &amp; IFA POSITIVE</td>
<td>240</td>
</tr>
<tr>
<td>HIV COMBO 4(^{th}) GEN REPEAT REACTIVE &amp; IFA NEGATIVE</td>
<td>39</td>
</tr>
<tr>
<td>HIV COMBO 4(^{th}) GEN REPEAT REACTIVE &amp; RNA POSITIVE</td>
<td>17</td>
</tr>
<tr>
<td>HIV COMBO 4(^{th}) GEN REPEAT REACTIVE &amp; RNA NEGATIVE</td>
<td>13</td>
</tr>
<tr>
<td>HIV COMBO 4(^{th}) GEN RR &amp; STATE LAB HIV-2 ANTIBODY NOT DETECTED</td>
<td>35</td>
</tr>
</tbody>
</table>
## SDPHL Testing Summary

### HIV IFA VS HIV MULTISPOT
March 2011 to November 15, 2012

<table>
<thead>
<tr>
<th>Category</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>TOTAL SAMPLES TESTED</td>
<td>36</td>
</tr>
<tr>
<td>IFA POSITIVE &amp; MULTISPOT POSITIVE</td>
<td>25</td>
</tr>
<tr>
<td>IFA NEGATIVE AND MULTISPOT POSITIVE</td>
<td>1</td>
</tr>
<tr>
<td>IFA INCONCLUSIVE &amp; MULTISPOT POSITIVE</td>
<td>4</td>
</tr>
<tr>
<td>IFA NEGATIVE &amp; MULTISPOT NEGATIVE</td>
<td>6</td>
</tr>
</tbody>
</table>
Conclusion

- 4\textsuperscript{TH} Gen Combo Assay decreases window period; improves early detection
  - Picked up 17 acute infections
- $618,900 per person for early infection
- $1.39 M per person for late infection
- Cost savings: $772,000 per person
  - 13.1 M for 17 acute infections identified

Schackman et al, Medical Care, 44: 990-997 (2006)
Conclusion

- Fast TAT, enables STAT testing
- Random access
- Initial and repeat testing same day
- System easy to use; happy staff
- Labor saving; happy staff and lab director
- Onboard reagent refrigeration
- System interfaced with StarLIMS
Acknowledgments

- Abbott Diagnostics
  - Dr. Ramani S. Wonderling
  - Rosemarie Munoz
- San Diego County Public Health Laboratory
  - Dr. Patricia McVay
  - Jill Giesick
  - Serology staff
  - Menka Asudani
  - Kris Pinto
- STD/HIV and Hepatitis Branch

- County of San Diego, Epidemiology & Immunization Services, Epidemiology Program
  - Lorri Freitas
- APHL
- CDC
Thank you for your time and attention!