Comparative Performance of the Avioq HIV-1 Microelisa System for the Detection of Antibodies to HIV-1 in Oral Fluid: A Review of the First Four Months of Utilization

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Objective

• To compare the performance of the Avioq HIV-1 Microelisa System with OraSure® specimens* to a 3rd generation blood-based EIA (BioRad HIV-1/2 Plus O EIA) previously validated in-house.

*Introduced in September 2009 after the former FDA approved method, Oral Fluid Vironostika® HIV-1 Microelisa System was withdrawn from the U.S. market in 2007. The Avioq HIV-1 Microelisa System is for the qualitative detection of antibodies to HIV-1 in human specimens collected as serum, plasma, dried blood spots or oral fluid specimens obtained with OraSure® HIV-1 Oral Specimen Collection Device. – Avioq HIV-1 Microelisa System [package insert]
OraSure® use in Florida’s Public Health Population

• In 2011, health departments reported 1,384,273 conventional laboratory tests were performed in the U.S., of these tests only 98,379 (7%) were performed on oral fluids. In addition between 2009 and 2011 the number of conventional oral fluid tests decreased by nearly 30%.*

• Laboratory-based OraSure® testing in Florida’s public health sector has declined by only 6% from 2009 (44,932) to 2011 (41,994) of these

  45% CBOs & FBOs w/limited staffing and often lack of liability insurance.

  17% drug treatment facilities

  9% outreach/field settings (bars, parks, homeless camps, etc.)

  5% jails/correctional settings with restrictions on needle use within their facilities.

  24% other, including clinical settings

* 2012 Testing Survey Report, NASTAD
Avioq HIV-1 EIA

reactive nonreactive

rpt.EIA in duplicate report as negative for HIV-1

one or both reactive both nonreactive

HIV-1 Orasure Western Blot

positive negative indeterminate

Report as HIV-1 Negative Report as HIV-1 Inconclusive

Report as HIV-1 positive
• Sensitivity and specificity data was based on prospective testing of fresh OraSure specimens.

• 9,543 OraSure specimens were tested by the Avioq HIV-1 EIA from August to November 2010.

• 10,620 OraSure specimens were tested by the BioRad HIV-1/2 Plus O EIA from April to July 2010.

• HIV-1 Western Blot (OraSure Technologies, Inc.) was performed on all repeatedly reactive screening results from both assays.
RESULTS (Sensitivity)

- Of the 9,543 OraSure specimens tested by the Avioq HIV-1 EIA
  - 216 (2.2%) were EIA repeatedly reactive, WB positive.
  - 1 (FN) was EIA nonreactive, WB inconclusive (p24 only), Clearview Complete reactive and proof of positivity on redraw. (Table 1)
  
  Avioq Sensitivity = 99.5% (216/217)

- Of the 10,620 Orasure specimens tested by the BioRad HIV-1/2 Plus O EIA
  - 224 (2.1%) were EIA repeatedly reactive, WB positive.

  BioRad Sensitivity = 100% (224/224)
RESULTS (Specificity)

- 9,317 were Avioq HIV-1 EIA nonreactive.
  9 (FP) were Avioq EIA r/r, WB negative (no bands).
  (Table 1)

  Avioq Specificity = 99.9% (9317/9326)

- 10,085 were BioRad HIV-1/2 Plus O EIA nonreactive.
  311 (FP) were BioRad EIA r/r, WB negative (no bands).

  BioRad Specificity = 97.1% (10085/10396)
<table>
<thead>
<tr>
<th>Specimen ID</th>
<th>Avioq EIA S/CO</th>
<th>Avioq EIA rpt. S/CO</th>
<th>WB bands</th>
<th>Follow up</th>
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</thead>
<tbody>
<tr>
<td>10518196</td>
<td>1.062</td>
<td>0.951 , 1.037</td>
<td>none</td>
<td>none</td>
</tr>
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<td>10518540</td>
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<td>1.547 , 1.562</td>
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<td>10519390</td>
<td>1.271</td>
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<td>Avioq (oral) nonreactive &lt;60 days</td>
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<td>2.865 , 2.807</td>
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<td>1.617 , 1.488</td>
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<td>none</td>
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<td>10525400</td>
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<td>3.144 , 2.557</td>
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<td>BioRad (blood) nonreactive &lt; 2 weeks</td>
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<td>10525438</td>
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<td>1.077 , 1.074</td>
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<td>BioRad (blood) nonreactive &lt; 2 weeks</td>
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<td>1.621, 1.483</td>
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<td>10523746</td>
<td>0.607</td>
<td>0.336 , 0.371</td>
<td>p24</td>
<td>Clearview reactive Avioq/WB Reactive on redraw &lt;60 days</td>
</tr>
</tbody>
</table>

False positives
False negative
Summary

• Our move to the FDA approved Avioq HIV-1 EIA reduced the number of repeatedly reactive screening results for supplemental testing.

• The study demonstrated a continued need to monitor Avioq HIV-1 EIA sensitivity by
  - our in-house policy to perform Avioq EIA and WB on all OraSures submitted with preliminary positive POC rapid results.
  - provider feedback (limited)

• Since our mid-year 2010 move to Avioq HIV-1 EIA it has required us to maintain two different screening platforms.
Conclusions

• The FBPHL will continue to support the FL Office of HIV/AIDS Prevention Program efforts to provide oral fluid testing primarily in non-clinical settings where obtaining blood samples is not feasible.

• Even with our recent transition of the blood-based testing to the new HIV Diagnostic Algorithm, we estimate only 20-30% of the OraSure testing volume is subject to possible blood-based testing.
Currently being formatted for publication and should be available on www.aphl.org in February 2013.

Includes current laboratory and program issues related to laboratory-based and POC oral fluid testing.
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