Field-oriented rapid diagnostics for early diagnosis of HIV infection

Baruch Rivetz PhD
Orgenics LTD, Yavne, Israel
Acute HIV diagnostic time-line

Adapted from Pilcher et al, 2004
Acute HIV Infection

Definition: Time interval during which HIV can be detected in blood before the formation of antibodies routinely used to diagnose infection. This interval is called “Window Period”

Characterized by:
• Lasts weeks to months
• High level of viremia
• Absence of detectable adaptive immune response
• Wide dissemination of virus
• Seeding of lymphoid organs
• Infected patients are highly infectious
• Lack of specific signs of retroviral infection
• Symptomatic phase of acute HIV mimics many common febrile illnesses such as mononucleosis
Strategies for HIV Diagnosis Improvement

- Application of new markers for early HIV infection to shorten seroconversion window
- Simplification of tests and shortening time of assay: development of rapid tests, use of other body fluids rather than serum/plasma (whole blood [DBS], oral, semen and genital fluid, urine); immediate results and counseling; avoiding return visits; addressing point-of-care use and emergency blood testing.
- New testing algorithms, utilizing new technologies, low-cost tests and avoiding unnecessary tests.
Advantages of rapid tests

- Accuracy. Rapid tests are as sensitive, specific and reproducible as EIAs
- Enable decentralization of HIV testing and counselling
- Feasible for limited laboratory infrastructure settings
- Acceptability of HIV testing to patients and counsellors
- Short time to obtain test results
- Cost effective
- Ease of performance and ease of test results interpretation
- Minimal facilities for storage and shelf-life
- Flexibility in numbers of tests performed
- Reduction in occupational exposure risk
Orgenics’ HIV test repertoire

ImmunoComb Platform
- ImmunoComb HIV 1&2 BiSpot
- ImmunoComb HIV 1&2 Combfirm
- ImmunoComb HIV 1&2 TriSpot Ag/Ab

Individual Rapid tests
- DoubleCheck II HIV 1&2
- Genie (Developed for Bio-Rad)
- DoubleCheckGold HIV 1&2
- DoubleCheckGold HIV 1&2 Ultra
- Determine® HIV ½ Ag/Ab Combo
Example of seroconversion panel (BCP 6246) in Determine® HIV-1/2 Ag/Ab Combo assay
The Determine® HIV-1/2 Ag/Ab Combo detects HIV infection 2-37 days earlier than the HIV 3rd generation antibody test, depending on the panel tested.
ImmunoComb
ImmunoComb HIV Ag/Ab TriSpot Performance

Seroconversion panel BBI BI

Days since 1st bleeding
# ImmunoComb HIV Ag/Ab TriSpot Performance

## Seroconversion panels: Days of Detection

<table>
<thead>
<tr>
<th>Panel</th>
<th>Reference p24 Antigen Test</th>
<th>Reference 3rd Gen EIA</th>
<th>ImmunoComb TriSpot HIV-1 p24 Ag</th>
<th>ImmunoComb TriSpot HIV-1 Ab</th>
<th>Gained days Compared to 3rd Generation EIA</th>
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<tr>
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<tr>
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<td>9</td>
<td>7</td>
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</tbody>
</table>

The ImmunoComb HIV TriSpot detects HIV infection 2 to 13 days earlier than 3rd-generation EIA.
ImmunoComb® II HCV

A third-generation test for qualitative detection of anti HCV IgG antibodies in human serum or plasma.

Simultaneous and differential detection of antibodies to Core and non-structural Antigens (NS3, NS4, NS5)

Test duration – 36 minutes at room temperature

Internal Control
HCV Core
HCV NS3, NS4, NS5
ImmunoComb® II HBs Ag

A test for the qualitative detection of hepatitis B virus surface antigen (HBsAg) in human serum or plasma.

Performance:
Sensitivity = 99%
Specificity = 100%
Test Duration: 90 minutes at 37C
Threshold = 0.5 ng/mL
Features:

Specimen: Whole blood (EDTA), plasma and serum

Specimen volume: 50 µl

Running time: 20 minutes

Analytical sensitivity:
  
  Current: 4 ng/ml
  Feasibility: 0.5 ng/ml

Specificity (In-house studies): 100%
Conclusions

The sequential use of the Determine® HIV ½ Ag/Ab Combo as an initial screening test and ImmunoComb HIV 1&2 TriSpot Ag/Ab as a confirmatory test provides a field-oriented, rapid, economical and complete high performance diagnostic system that may suit Blood Banks and transfusion centers in out-of-hospital emergencies during disasters or any other blood crisis. Field-oriented diagnosis for HBV and HCV that can be used in the same circumstances is available as well.
Thanks

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• Amos
• Dorit
• Falk
• Ileana
• Lindy
• Oren
• Tomer
• Vivian
• Yifat

Unipath:
• Gani et al*

* Part time

IMJ:
• Karasawa-san*
• Tamanoue-san*
• Tanaka-san*
• Asahina-san*
• Miwa-san*

Abbott:
R&D scientists of greater Abbott who developed the Determine® platform