Centers for Disease Control and Prevention
Model Performance Evaluation Program

Human T-Lymphotrophic Virus
Types I and II (HTLV-I/II) Testing

Figures Used to Summarize the
Participant Laboratory Results
for the May 2001 Shipment

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention
Public Health Practice Program Office
Division of Laboratory Systems
Atlanta, Georgia 30341-3717

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Table 1

<table>
<thead>
<tr>
<th>Panel Letter</th>
<th>Vial Label</th>
<th>CDC Donor Number</th>
<th>CDC Contractor Result&lt;sup&gt;2&lt;/sup&gt;</th>
<th>Laboratory Interpretation&lt;sup&gt;1&lt;/sup&gt;</th>
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</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>INIT.&lt;sup&gt;3&lt;/sup&gt;  FINAL&lt;sup&gt;4&lt;/sup&gt;  WB  IIF</td>
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<tr>
<td>A</td>
<td>A1, A6</td>
<td>1</td>
<td>Negative</td>
<td>___  ___  ___  ___</td>
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<tr>
<td>A</td>
<td>A2, A5</td>
<td>2</td>
<td>Positive, HTLV-II</td>
<td>___  ___  ___  ___</td>
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<tr>
<td>A</td>
<td>A3</td>
<td>3</td>
<td>Positive, HTLV-I</td>
<td>___  ___  ___  ___</td>
</tr>
<tr>
<td>A</td>
<td>A4</td>
<td>4</td>
<td>Negative</td>
<td>___  ___  ___  ___</td>
</tr>
<tr>
<td>B</td>
<td>B1</td>
<td>3</td>
<td>Positive, HTLV-I</td>
<td>___  ___  ___  ___</td>
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<tr>
<td>B</td>
<td>B2, B4</td>
<td>2</td>
<td>Positive, HTLV-II</td>
<td>___  ___  ___  ___</td>
</tr>
<tr>
<td>B</td>
<td>B3, B5</td>
<td>1</td>
<td>Negative</td>
<td>___  ___  ___  ___</td>
</tr>
<tr>
<td>B</td>
<td>B6</td>
<td>4</td>
<td>Negative</td>
<td>___  ___  ___  ___</td>
</tr>
</tbody>
</table>

<sup>1</sup> Laboratory Interpretation space (to be completed by participant laboratory) provided to facilitate comparison of participant laboratory result with CDC result.

<sup>2</sup> The CDC result was obtained after composite EIA, WB, and RIPA testing, by CDC contractor, and employing the interpretation criteria of the Public Health Service Working Group.

<sup>3</sup> Initial EIA interpretation

<sup>4</sup> Final EIA interpretation
Figure 1. Frequency of HTLV-I/II antibody test result interpretations, by sample type (reactivity), for enzyme immunoassay (EIA), Western blot (WB), and indirect immunofluorescence (IIF), reported by participant laboratories for the May 2001 shipment.

**ENZYME IMMUNOASSAY**

- **N = 180**
- Frequency of Interpretation
  - Negative: 540
  - Positive: 541

* = Indeterminate is not an EIA interpretation option; these areas have been left blank.

**WESTERN BLOT**

- **N = 28**
- Frequency of Interpretation
  - Negative: 37
  - Positive: 79

**INDIRECT IMMUNOFLUORESCENCE**

- **N = 2**
- Frequency of Interpretation
  - Negative: 9
  - Positive: 7

Test Result Interpretations
- Non-Reactive
- Indeterminate
- Reactive

CDC Model Performance Evaluation Program
HTLV-I/II Antibody Testing
Figure 2. Percentage of HTLV-I/II participant laboratories, by laboratory type, that reported EIA, WB, and IIF results to the CDC for the May 2001 shipment.

- **EIA**
  - Blood Bank: 81
  - Hospital: 56
  - Independent: 17
  - Other: 17
  - N = 180

- **WB**
  - Blood Bank: 9
  - Hospital: 5
  - Independent: 5
  - Other: 5
  - N = 28

- **IIF**
  - N = 2

Figure 3. Combination of HTLV-I/II antibody tests reported by participant laboratories for the May 2001 shipment.

- **EIA**
  - EIA: 152
  - EIA, WB: 18
  - EIA, Other: 5
  - WB: 3
  - EIA, WB, Other: 3
  - WB, Other: 3
  - EIA, IIF, Other: 1
  - N = 186
Figure 4. Types of HTLV-I/II antibody test kits used for enzyme immunoassay, Western blot, and indirect immunofluorescence, as reported by participant laboratories to the CDC for the May 2001 shipment.
Figure 5. Enzyme immunoassay HTLV-I/II antibody test results, by kit manufacturer, reported by participant laboratories for the May 2001 shipment

SAMPLE REACTIVITY -- NEGATIVE

N = 180

SAMPLE REACTIVITY -- POSITIVE

N = 180
Figure 6. Western blot HTLV-I/II antibody test results, by kit manufacturer, reported by participant laboratories for the May 2001 shipment.
Figure 7. Indirect immunofluorescence HTLV-I/II antibody test results, by kit manufacturer, reported by participant laboratories for the May 2001 shipment.

**SAMPLE REACTIVITY -- NEGATIVE**

- Frequency of Results
- In House
- N = 2

**SAMPLE REACTIVITY -- POSITIVE**

- Frequency of Results
- In House
- N = 2

Test Result Interpretations
- Non-Reactive
- Indeterminate
- Reactive
Figure 8. Western blot HTLV-I/II antibody band patterns reported to CDC by participant laboratories for the May 2001 shipment

<table>
<thead>
<tr>
<th>CDC Donor #</th>
<th>Donor HTLV Status</th>
<th>Number of Reports</th>
<th>Band Patterns Reported</th>
<th>Percentage of Reports</th>
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<td>Uninfected</td>
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<td>P19 4 1 0 0 0 0 0 0</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>r21e 0 0 0 0 0 0 0 0</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>GD21 0 0 0 0 0 0 0 0</td>
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</tr>
<tr>
<td>02</td>
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<td></td>
<td></td>
<td></td>
<td>r21e 0 0 0 0 0 0 0 0</td>
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<td></td>
<td></td>
<td></td>
<td>GD21 0 0 0 0 0 0 0 0</td>
<td></td>
</tr>
<tr>
<td>03</td>
<td>Infected</td>
<td>N = 28</td>
<td>P19 28 27 28 25 23 19</td>
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<td></td>
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<td>r21e 0 0 0 0 0 0 0 0</td>
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<td></td>
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<td></td>
<td>GD21 0 0 0 0 0 0 0 0</td>
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<tr>
<td>04</td>
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<td>N = 13</td>
<td>P19 0 0 0 0 0 0 0 0 0</td>
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<td>r21e 0 0 0 0 0 0 0 0 0</td>
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<td></td>
<td></td>
<td></td>
<td>GD21 0 0 0 0 0 0 0 0 0</td>
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</tbody>
</table>
Figure 9. Fluorescence intensity patterns, of HTLV-I/II-infected cells, for IIF results reported to CDC by participant laboratories for the May 2001 shipment

<table>
<thead>
<tr>
<th>CDC Donor #</th>
<th>Donor HTLV Status</th>
<th>Intensity Reported</th>
<th>Number of Reports</th>
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<tbody>
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<td>6</td>
<td>N = 6</td>
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<tr>
<td>02</td>
<td>Infected</td>
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<td>3</td>
<td>N = 3</td>
</tr>
</tbody>
</table>
Figure 10. Types of 'Other' HTLV antibody test kits used and results reported by participant laboratories to the CDC for the May 2001 shipment

**OTHER KIT MANUFACTURER**

N = 12

**SAMPLE REACTIVITY -- NEGATIVE**

N = 9

**SAMPLE REACTIVITY -- POSITIVE**

N = 12