Centers for Disease Control and Prevention
Model Performance Evaluation Program

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

Figures Used to Summarize the
Participant Laboratory Results
for the November 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</th>
<th>Laboratory Interpretation¹</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>A1, A4</td>
<td>3</td>
<td>Positive, HTLV-I</td>
<td></td>
</tr>
<tr>
<td>A2</td>
<td>1</td>
<td>Negative</td>
<td></td>
<td></td>
</tr>
<tr>
<td>A3</td>
<td>2</td>
<td>Positive, HTLV-II</td>
<td></td>
<td></td>
</tr>
<tr>
<td>A5, A6</td>
<td>4</td>
<td>Negative</td>
<td></td>
<td></td>
</tr>
<tr>
<td>B</td>
<td>B1, B6</td>
<td>4</td>
<td>Negative</td>
<td></td>
</tr>
<tr>
<td>B2</td>
<td>1</td>
<td>Negative</td>
<td></td>
<td></td>
</tr>
<tr>
<td>B3</td>
<td>2</td>
<td>Positive, HTLV-II</td>
<td></td>
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</tr>
<tr>
<td>B4, B5</td>
<td>3</td>
<td>Positive, HTLV-I</td>
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</table>

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

² 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.

³ Initial EIA interpretation

⁴ 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 November 2001 shipment.

**ENZYME IMMUNOASSAY**

- **N = 179**
- **Negative**: 537
- **Positive**: 544
- * = Indeterminate is not an EIA interpretation option; these areas have been left blank

**WESTERN BLOT**

- **N = 26**
- **Negative**: 35
- **Positive**: 77

**INDIRECT IMMUNOFLUORESCENCE**

- **N = 2**
- **Negative**: 9
- **Positive**: 9

Test Result Interpretations

- Non-Reactive
- Indeterminate
- Reactive
Figure 2. Percentage of HTLV-I/II participant laboratories, by laboratory type, that reported EIA, WB, and IIF results to the CDC for the November 2001 shipment

- EIA: N = 179
  - Blood Bank: 80%
  - Hospital: 19%
  - Independent: 16%
  - Other: 11%

- WB: N = 26
  - Blood Bank: 6%
  - Hospital: 6%
  - Independent: 5%
  - Other: 5%

- IIF: N = 2
  - Blood Bank: 4%
  - Hospital: 1%
  - Independent: 1%
  - Other: 1%

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

- EIA: N = 186
- EIA, WB: 153
- EIA, Other: 18
- WB, Other: 2
- EIA, WB, Other: 1
- EIA, IIF, Other: 1
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 November 2001 shipment.

- **EIA KIT MANUFACTURER**
  - N = 179
  - Abbott HTLV-I/HTLV-II
  - Organon Teknika HTLV-I/II
  - Murex Diagnostics (Abbott)
  - Ortho HTLV-I/HTLV-II
  - Other
  - Pasteur Diagnostics (Sanofi)
  - BioChem Immunosystems

- **WB KIT MANUFACTURER**
  - N = 26
  - Genelabs Diagnostics
  - Diagnostic Biotech
  - Cambridge Biotech
  - Calypso
  - Other
  - In House

- **IIF KIT MANUFACTURER**
  - N = 2
  - In House
Figure 5. Enzyme immunoassay HTLV-I/II antibody test results, by kit manufacturer, reported by participant laboratories for the November 2001 shipment.

SAMPLE REACTIVITY -- NEGATIVE

N = 178

SAMPLE REACTIVITY -- POSITIVE

N = 179
Figure 6. Western blot HTLV-I/II antibody test results, by kit manufacturer, reported by participant laboratories for the November 2001 shipment

**SAMPLE REACTIVITY -- NEGATIVE**

- **N = 13**

**SAMPLE REACTIVITY -- POSITIVE**

- **N = 26**

Test Result Interpretations:
- Non-Reactive
- Indeterminate
- Reactive
Figure 7. Indirect immunofluorescence HTLV-I/II antibody test results, by kit manufacturer, reported by participant laboratories for the November 2001 shipment.

**SAMPLE REACTIVITY -- NEGATIVE**

- Frequency of Results
- N = 2

**SAMPLE REACTIVITY -- POSITIVE**

- Frequency of Results
- 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 November 2001 shipment

<table>
<thead>
<tr>
<th>CDC Donor #</th>
<th>Donor HTLV Status</th>
<th>Band Patterns Reported</th>
<th>Number of Reports</th>
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<tr>
<td>01</td>
<td>Uninfected</td>
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<td>N = 13</td>
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<tr>
<td></td>
<td></td>
<td>P19 r21e GD21</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>P24 P32 GP46 r46I r46II GP61 GP68</td>
<td></td>
</tr>
<tr>
<td>02</td>
<td>Infected</td>
<td></td>
<td>N = 26</td>
</tr>
<tr>
<td></td>
<td></td>
<td>P19 r21e GD21</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>P24 P32 GP46 r46I r46II GP61 GP68</td>
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<td>03</td>
<td>Infected</td>
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<td>N = 52</td>
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<tr>
<td></td>
<td></td>
<td>P19 r21e GD21</td>
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<tr>
<td></td>
<td></td>
<td>P24 P32 GP46 r46I r46II GP61 GP68</td>
<td></td>
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<tr>
<td>04</td>
<td>Uninfected</td>
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<td>N = 26</td>
</tr>
<tr>
<td></td>
<td></td>
<td>P19 r21e GD21</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>P24 P32 GP46 r46I r46II GP61 GP68</td>
<td></td>
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</table>
Figure 9. Fluorescence intensity patterns, of HTLV-I/II-infected cells, for IIF results reported to CDC by participant laboratories for the November 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>Uninfected</td>
<td>0+ 1+ 2+ 3+ 4+</td>
<td>N = 3</td>
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<tr>
<td>02</td>
<td>Infected</td>
<td>0+ 1+ 2+ 3+ 4+</td>
<td>N = 3</td>
</tr>
<tr>
<td>03</td>
<td>Infected</td>
<td>0+ 1+ 2+ 3+ 4+</td>
<td>N = 6</td>
</tr>
<tr>
<td>04</td>
<td>Uninfected</td>
<td>0+ 1+ 2+ 3+ 4+</td>
<td>N = 6</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Percentage of Reports</th>
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<tbody>
<tr>
<td>0 0 0 0 0</td>
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<td>0 1 2 0 0</td>
</tr>
<tr>
<td>0 2 2 2 0</td>
</tr>
<tr>
<td>6 0 0 0 0</td>
</tr>
</tbody>
</table>

N = 301 Uninfected
N = 302 Infected
N = 603 Infected
N = 604 Uninfected
Figure 10. Types of ‘Other’ HTLV antibody test kits used and results reported by participant laboratories to the CDC for the November 2001 shipment

- **OTHER KIT MANUFACTURER**
  - N = 12
  - Abbott: 5
  - Fujirebio: 5
  - InnoGen: 2
  - In House: 1

- **SAMPLE REACTIVITY -- NEGATIVE**
  - N = 8
  - Abbott: 5
  - Fujirebio: 15
  - InnoGen: 3

- **SAMPLE REACTIVITY -- POSITIVE**
  - N = 12
  - Abbott: 6
  - Fujirebio: 15
  - In House: 1
  - Indeterminate: 2
  - Reactive: 15

*Test Result Interpretations*
- Non-Reactive
- Indeterminate
- Reactive
Figure 11. HTLV-I/II antigen lines reported to CDC by participant laboratories using INNO-LIA for the November 2001 shipment

<table>
<thead>
<tr>
<th>CDC Donor #</th>
<th>Donor HTLV Status</th>
<th>Antigen Lines Reported</th>
<th>Number of Reports</th>
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</thead>
<tbody>
<tr>
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<td>Uninfected</td>
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<td>0 0 0 0</td>
</tr>
<tr>
<td>02</td>
<td>Infected</td>
<td>p19 I/II p24 I/II gp46 I/II gp21 I/II</td>
<td>5 5 5 5</td>
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<tr>
<td>03</td>
<td>Infected</td>
<td>p19 I/II p24 I/II gp46 I/II gp21 I/II</td>
<td>10 10 10 10</td>
</tr>
<tr>
<td>04</td>
<td>Uninfected</td>
<td>p19 I/II p24 I/II gp46 I/II gp21 I/II</td>
<td>0 0 0 0</td>
</tr>
</tbody>
</table>