Centers for Disease Control and Prevention
Model Performance Evaluation Program

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

Figures Used to Summarize the Participant Laboratory Results for the November 2, 1998 Shipment

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention
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Centers for Disease Control and Prevention (CDC)
Model Performance Evaluation Program
Human T-Lymphotrophic Virus Types I and II (HTLV-I/II) Testing
November 2, 1998 Participant Laboratory Shipment

Table 1

<table>
<thead>
<tr>
<th>Panel Letter</th>
<th>Vial Label</th>
<th>CDC Donor Number</th>
<th>CDC Result</th>
<th>Laboratory Interpretation¹</th>
</tr>
</thead>
<tbody>
<tr>
<td>E</td>
<td>E1,E3</td>
<td>13</td>
<td>Negative</td>
<td>INIT. ³      FINAL ⁴      WB   IIF</td>
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<tr>
<td></td>
<td>E4</td>
<td>09</td>
<td>Negative</td>
<td></td>
</tr>
<tr>
<td></td>
<td>E5</td>
<td>05</td>
<td>Positive, HTLV-II</td>
<td></td>
</tr>
<tr>
<td></td>
<td>E2,E6</td>
<td>01</td>
<td>Positive, HTLV-I</td>
<td></td>
</tr>
<tr>
<td>F</td>
<td>F5</td>
<td>10</td>
<td>Negative</td>
<td></td>
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<td></td>
<td>F2,F4</td>
<td>14</td>
<td>Negative</td>
<td></td>
</tr>
<tr>
<td></td>
<td>F6</td>
<td>06</td>
<td>Positive, HTLV-II</td>
<td></td>
</tr>
<tr>
<td></td>
<td>F1,F3</td>
<td>02</td>
<td>Positive, HTLV-I</td>
<td></td>
</tr>
<tr>
<td>G</td>
<td>G1</td>
<td>07</td>
<td>Positive, HTLV-II</td>
<td></td>
</tr>
<tr>
<td></td>
<td>G6</td>
<td>11</td>
<td>Negative</td>
<td></td>
</tr>
<tr>
<td></td>
<td>G3,G5</td>
<td>15</td>
<td>Negative</td>
<td></td>
</tr>
<tr>
<td></td>
<td>G2,G4</td>
<td>03</td>
<td>Positive, HTLV-I</td>
<td></td>
</tr>
<tr>
<td>H</td>
<td>H3,H5</td>
<td>04</td>
<td>Positive, HTLV-I</td>
<td></td>
</tr>
<tr>
<td></td>
<td>H2</td>
<td>08</td>
<td>Positive, HTLV-II</td>
<td></td>
</tr>
<tr>
<td></td>
<td>H1</td>
<td>12</td>
<td>Negative</td>
<td></td>
</tr>
<tr>
<td></td>
<td>H4,H6</td>
<td>16</td>
<td>Negative</td>
<td></td>
</tr>
</tbody>
</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
SUPPLEMENTAL INFORMATION FOR COMPREHENDING
THE NUMBERS USED TO LABEL FIGURES
IN THIS REPORT

The "N-" that appears on each graph represents the number of laboratories that reported results. For some graphs, laboratories reported results using more than one test; therefore, the number of results may exceed the actual number of laboratories providing reports. In figures 1-7 and 10, the vertical axis is labeled either as frequency or percentage of results; in figures 8 and 9, this axis is labeled as percentage of reports. However, in all figures, the number appearing directly above or within each bar represents a frequency of results only.
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 2, 1998 shipment.

**ENZYME IMMUNOASSAY**

- **N = 189**
- Frequency of Interpretation:
  - Negative: 570
  - Positive: 573

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

**WESTERN BLOT**

- **N = 30**
- Frequency of Interpretation:
  - Negative: 62
  - Positive: 91

**INDIRECT IMMUNOFLUORESCENCE**

- **N = 3**
- Frequency of Interpretation:
  - Negative: 12
  - Positive: 12

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 November 2, 1998 shipment.

**EIA**
- **N = 189**
- Percentage:
  - Blood Bank: 87
  - Hospital: 61
  - Independent: 20
  - Health Dept: 14
  - Other: 7

**WB**
- **N = 30**
- Percentage:
  - Blood Bank: 10
  - Hospital: 7
  - Independent: 6
  - Health Dept: 4
  - Other: 3

**IIF**
- **N = 3**
- Percentage:
  - Blood Bank: 1
  - Hospital: 1
  - Independent: 1
  - Health Dept: 0
  - Other: 0

Figure 3. Combination of HTLV-I/II antibody tests reported by participant laboratories for the November 2, 1998 shipment.

**Test Combinations**
- **N = 192**
- EIA only: 160
- EIA and WB: 27
- WB only: 2
- EIA, WB, and IIF: 1
- EIA and IIF: 1
- IIF only: 1

CDC Model Performance Evaluation Program
HTLV-I/II Antibody Testing
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 2, 1998 shipment.
Figure 5. Enzyme immunoassay HTLV-I/II antibody test results, by kit manufacturer, reported by participant laboratories for the November 2, 1998 shipment.
Figure 6. Western blot HTLV-I/II antibody test results, by kit manufacturer, reported by participant laboratories for the November 2, 1998 shipment

SAMPLE REACTIVITY -- NEGATIVE

N = 21

SAMPLE REACTIVITY -- POSITIVE

N = 30
Figure 7. Indirect immunofluorescence HTLV-I/II antibody test results, by kit manufacturer, reported by participant laboratories for the November 2, 1998 shipment.
Figure 8. Western blot HTLV-I/II antibody band patterns reported to CDC by participant laboratories for the November 2, 1998 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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</thead>
<tbody>
<tr>
<td>01</td>
<td>Infected</td>
<td>16 14 16 14 14 4 2 0 0</td>
<td>N = 16</td>
</tr>
<tr>
<td>02</td>
<td>Infected</td>
<td>16 16 18 18 18 12 2 0 0</td>
<td>N = 18</td>
</tr>
<tr>
<td>03</td>
<td>Infected</td>
<td>13 15 15 15 6 0 0 1 0</td>
<td>N = 16</td>
</tr>
<tr>
<td>04</td>
<td>Infected</td>
<td>12 12 12 12 12 10 0 0 0</td>
<td>N = 12</td>
</tr>
<tr>
<td>05</td>
<td>Infected</td>
<td>8 7 8 7 5 1 2 0 0</td>
<td>N = 8</td>
</tr>
<tr>
<td>06</td>
<td>Infected</td>
<td>5 8 9 2 2 0 6 0 0</td>
<td>N = 9</td>
</tr>
<tr>
<td>07</td>
<td>Infected</td>
<td>7 8 8 3 3 0 3 0 0</td>
<td>N = 8</td>
</tr>
<tr>
<td>08</td>
<td>Infected</td>
<td>5 6 6 0 0 0 4 0 0</td>
<td>N = 6</td>
</tr>
</tbody>
</table>
Figure 8. Western blot HTLV-I/II antibody band patterns reported to CDC by participant laboratories for the November 2, 1998 shipment.

<table>
<thead>
<tr>
<th>CDC Donor #</th>
<th>Donor HTLV Status</th>
<th>Percentage of Reports</th>
<th>Band Patterns Reported</th>
<th>Number of Reports</th>
</tr>
</thead>
<tbody>
<tr>
<td>09</td>
<td>Uninfected</td>
<td></td>
<td>P19 r21e GD21 P24 P32 GP46 r46I r46II GP61 GP68</td>
<td>N = 6</td>
</tr>
<tr>
<td>10</td>
<td>Uninfected</td>
<td></td>
<td>P19 r21e GD21 P24 P32 GP46 r46I r46II GP61 GP68</td>
<td>N = 5</td>
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<tr>
<td>11</td>
<td>Uninfected</td>
<td></td>
<td>P19 r21e GD21 P24 P32 GP46 r46I r46II GP61 GP68</td>
<td>N = 7</td>
</tr>
<tr>
<td>12</td>
<td>Uninfected</td>
<td></td>
<td>P19 r21e GD21 P24 P32 GP46 r46I r46II GP61 GP68</td>
<td>N = 3</td>
</tr>
<tr>
<td>13</td>
<td>Uninfected</td>
<td></td>
<td>P19 r21e GD21 P24 P32 GP46 r46I r46II GP61 GP68</td>
<td>N = 12</td>
</tr>
<tr>
<td>14</td>
<td>Uninfected</td>
<td></td>
<td>P19 r21e GD21 P24 P32 GP46 r46I r46II GP61 GP68</td>
<td>N = 10</td>
</tr>
<tr>
<td>15</td>
<td>Uninfected</td>
<td></td>
<td>P19 r21e GD21 P24 P32 GP46 r46I r46II GP61 GP68</td>
<td>N = 14</td>
</tr>
<tr>
<td>16</td>
<td>Uninfected</td>
<td></td>
<td>P19 r21e GD21 P24 P32 GP46 r46I r46II GP61 GP68</td>
<td>N = 6</td>
</tr>
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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 2, 1998 shipment.

<table>
<thead>
<tr>
<th>CDC Donor #</th>
<th>Donor HTLV Status</th>
<th>Intensity Reported</th>
<th>Number of Reports</th>
</tr>
</thead>
<tbody>
<tr>
<td>01</td>
<td>Infected</td>
<td></td>
<td>N = 2</td>
</tr>
<tr>
<td>02</td>
<td>Infected</td>
<td></td>
<td>N = 4</td>
</tr>
<tr>
<td>03</td>
<td>Infected</td>
<td></td>
<td>No Tests Done</td>
</tr>
<tr>
<td>04</td>
<td>Infected</td>
<td></td>
<td>N = 2</td>
</tr>
<tr>
<td>05</td>
<td>Infected</td>
<td></td>
<td>N = 1</td>
</tr>
<tr>
<td>06</td>
<td>Infected</td>
<td></td>
<td>N = 2</td>
</tr>
<tr>
<td>07</td>
<td>Infected</td>
<td></td>
<td>No Tests Done</td>
</tr>
<tr>
<td>08</td>
<td>Infected</td>
<td></td>
<td>N = 1</td>
</tr>
</tbody>
</table>
Figure 9. Fluorescence intensity patterns, of HTLV-I/II-infected cells, for IIF results reported to CDC by participant laboratories for the November 2, 1998 shipment.
Figure 10. Types of 'Other' HTLV antibody test kits used and results reported by participant laboratories to the CDC for the November 2, 1998 shipment.

**OTHER KIT MANUFACTURER**

- Fujirebio: 2
- Chiron RIBA: 1
- In House: 1

**SAMPLE REACTIVITY -- NEGATIVE**

- Chiron RIBA: 3
- Fujirebio: 6

**SAMPLE REACTIVITY -- POSITIVE**

- Chiron RIBA: 3
- Fujirebio: 6
- In House: 1

Test Result Interpretations:
- Non-Reactive
- Indeterminate
- Reactive