HIV-1/2 Differentiation in the United States HIV Testing Algorithm: High Burden, Low Yield

ANNE PERUSKI

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Recommended Laboratory HIV Testing Algorithm for Serum or Plasma Specimens

HIV-1/2 antigen/antibody immunoassay

(+)

HIV-1/HIV-2 antibody differentiation immunoassay

HIV-1 (+)
HIV-2 (-)
HIV-1 Ab detected
(+ indicates reactive test results
(-) indicates nonreactive test results
NAT: nucleic acid test

(-)

Negative for HIV-1 and HIV-2 antibodies and p24 antigen

HIV-1 (-) or Indeterminate
and HIV-2 (-) or Indeterminate

HIV-1 NAT

NAT (+) Acute HIV-1 Infection
NAT (-) Negative for HIV-1

https://stacks.cdc.gov/view/cdc/50872
HIV-1/2 Differentiation Test

Geenius HIV-1/2 Supplemental (differentiation) assay
Serum, plasma, whole blood
~ 30 min
FDA approved 2014

Multispot HIV-1/2 Supplemental (differentiation) assay
Serum, plasma ~ 15 min
FDA approved 2004
Purpose

- Develop a definition to categorize type of HIV diagnoses in the National HIV Surveillance System (NHSS)
- Evaluate the number of HIV-2 diagnoses
- Describe the demographics of HIV-1 and HIV-2 infections
- Evaluate the extent of the use of the HIV-1/2 differentiation test
Data Source and Population

- Data reported to the United States NHSS through June 2018
- Persons aged ≥13 years with HIV infection diagnosed during 2012-2016
- Persons residing in the 50 United States, Washington DC, or six dependent areas at time of diagnosis
HIV diagnoses reported to the National HIV Surveillance System 2012-2016

Dual HIV-1 and HIV-2 diagnoses

HIV-2 diagnoses, confirmed

HIV-2 diagnoses, probable but not confirmed

HIV-1 diagnoses
Dual HIV-1 and HIV-2 diagnoses
HIV-2+ Ab or HIV-1+/HIV-2+ Ab
and
HIV-1+ RNA/DNA
and HIV-2+ RNA
HIV-2 diagnoses, confirmed
HIV-2+ RNA or HIV-2+ differentiating test
and
No HIV-1+ RNA/DNA
HIV-2 diagnoses, probable but not confirmed
HIV-2+ Ab
and
No HIV-1+ RNA/DNA
HIV-1 diagnoses
All remaining diagnoses
## Type of HIV diagnoses for persons aged ≥13 years with HIV diagnosed during 2012-2016—United States and 6 dependent areas

<table>
<thead>
<tr>
<th>Year of Diagnosis</th>
<th>2012 N=41,701</th>
<th>2013 N=40,036</th>
<th>2014 N=40,708</th>
<th>2015 N=40,394</th>
<th>2016 N=40,012</th>
<th>Total N=202,851</th>
<th>EAPC*</th>
<th>95% CI**</th>
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<tbody>
<tr>
<td>HIV-1 diagnoses</td>
<td>41,678</td>
<td>40,026</td>
<td>40,675</td>
<td>40,363</td>
<td>39,975</td>
<td>202,717</td>
<td>-0.01</td>
<td>(-0.01, -0.003)</td>
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<tr>
<td>Dual HIV-1/2 diagnoses</td>
<td>3</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>5</td>
<td>-42.6</td>
<td>(-72.7, 20.9)</td>
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<tr>
<td>HIV-2 diagnoses, confirmed</td>
<td>8</td>
<td>8</td>
<td>23</td>
<td>15</td>
<td>19</td>
<td>73</td>
<td>23.2</td>
<td>(4.4, 45.5)</td>
</tr>
<tr>
<td>HIV-2 diagnoses, probable but not confirmed</td>
<td>12</td>
<td>2</td>
<td>9</td>
<td>15</td>
<td>18</td>
<td>56</td>
<td>26.4</td>
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*estimated annual percent change  
**confidence interval
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Characteristics of persons aged ≥13 years with HIV diagnosed during 2012-2016—United States and 6 dependent areas
Characteristics of persons aged ≥13 years with HIV diagnosed during 2012-2016—United States and 6 dependent areas

- Black/African American
- Hispanic/Latino
- White
- Other

- MSM
- IDU
- MSM/IDU
- Hetero
- NIR
- Other

HIV-1
HIV-2
Characteristics of persons aged ≥13 years with HIV diagnosed during 2012-2016—United States and 6 dependent areas
### Differentiation testing among persons aged ≥13 years with HIV diagnosed during 2012-2016—United States and 6 dependent areas

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<thead>
<tr>
<th>Year</th>
<th>N</th>
<th>Persons tested with an HIV-1/2 differentiation test N (%)</th>
<th>Persons with an HIV-2 or HIV-1 and HIV-2 positive differentiation test result N (%)</th>
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<tr>
<td>2012</td>
<td>41,701</td>
<td>10,019 (24.0)</td>
<td>37 (0.1)</td>
</tr>
<tr>
<td>2013</td>
<td>40,036</td>
<td>14,092 (35.2)</td>
<td>38 (0.1)</td>
</tr>
<tr>
<td>2014</td>
<td>40,708</td>
<td>26,143 (64.7)</td>
<td>107 (0.3)</td>
</tr>
<tr>
<td>2015</td>
<td>40,394</td>
<td>31,592 (80.7)</td>
<td>120 (0.3)</td>
</tr>
<tr>
<td>2016</td>
<td>40,012</td>
<td>32,308 (80.7)</td>
<td>100 (0.2)</td>
</tr>
<tr>
<td>Total</td>
<td>202,851</td>
<td>114,154 (56.3)</td>
<td>402 (0.2)</td>
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Differentiation testing among persons aged ≥13 years with HIV-1 diagnosed during 2012-2016—United States and 6 dependent areas

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<td>40,036</td>
<td>14,085 (35.2)</td>
<td>31 (0.1)</td>
</tr>
<tr>
<td>2014</td>
<td>40,708</td>
<td>26,115 (64.2)</td>
<td>81 (0.2)</td>
</tr>
<tr>
<td>2015</td>
<td>40,394</td>
<td>31,564 (78.2)</td>
<td>101 (0.3)</td>
</tr>
<tr>
<td>2016</td>
<td>40,012</td>
<td>32,274 (80.7)</td>
<td>75 (0.2)</td>
</tr>
<tr>
<td>Total</td>
<td>202,851</td>
<td>114,047 (56.3)</td>
<td>317 (0.2)</td>
</tr>
</tbody>
</table>
Trends in differentiation testing among persons aged ≥13 years with HIV-1 diagnosed during 2012-2016—United States and 6 dependent areas

HIV-1 Diagnoses

- Persons tested with an HIV-1/2 differentiation test N (%)
- Persons with an HIV-2 or HIV-1/2 positive HIV-1/2 differentiation test N (%)

Percent tested with a differentiation test

Percent with an HIV-2 + differentiation test result

27 EAPC

31 EAPC

Summary

- Overall, 99.9% of all HIV infections diagnosed were HIV-1
- The number of HIV-2 diagnoses remained extremely low
- There has been a significant increase in the use of HIV-1/2 differentiation tests, which is consistent with the implementation of the new guidelines for the United States HIV testing algorithm
Summary

- Overall, during 2012-2016 there were 73 persons with confirmed HIV-2 diagnoses; considerably less than the 317 with confirmed HIV-1 diagnoses that had conflicting differentiation test results.

- The demographics of persons with HIV-2 infection differ significantly from those with HIV-1 infection:
  - Persons with HIV-2 infection were more frequently older, female, black/African American, had no identified risk factor, were from HIV-2 endemic countries and resided in the northeast.
Summary

- The availability of additional FDA approved rapid and sensitive tests for diagnosis of HIV could lead to an improved HIV diagnostic algorithm
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Questions?