



## Department of Health

**ANDREW M. CUOMO**  
Governor

**HOWARD A. ZUCKER, M.D., J.D.**  
Commissioner

**SALLY DRESLIN, M.S., R.N.**  
Executive Deputy Commissioner

June 13, 2016

Re: 2016 Guidelines for use of the HIV Diagnostic Testing Algorithm for Laboratories

Dear Laboratory Director and Management Staff:

The purpose of this letter is to provide updated information to New York State (NYS) Permitted Clinical Laboratories performing diagnostic testing for human immunodeficiency virus (HIV). These updated guidelines supersede the Interim Guidelines for Laboratories on the use of the Diagnostic Testing Algorithm for Human Immunodeficiency Virus (HIV) Infection that were issued by the New York State Department of Health on May 16, 2013. Since that time, the following developments have occurred.

- On June 27, 2014, the Centers for Disease Control and Prevention (CDC) released Updated [Recommendations for Laboratory Testing for the Diagnosis of HIV Infection](#).
- Additional HIV diagnostic tests have received approval from the FDA.
- Bio-Rad Laboratories announced the discontinuation of the Multispot HIV-1/HIV-2 Rapid Test as of July 2016.
- Updated laboratory reporting requirements for HIV-related tests were released in the [2016 Edition of Laboratory Reporting of Communicable Diseases](#).

**The updated laboratory guidelines include the following attachments which have been posted on the NYSDOH website at <http://www.health.ny.gov/diseases/aids/providers/testing/index.htm>.**

- Attachment 1 The Recommended Laboratory HIV Testing Algorithm for Serum and Plasma Specimens released by the CDC on June 27, 2014
- Attachment 2 FDA-approved Test Methods Applicable to the HIV Diagnostic Testing Algorithm
- Attachment 3a Guidance for Reporting Results of the Recommended HIV Diagnostic Testing Algorithm to Providers and the NYSDOH – [Analyte Non-differentiating HIV Ag/Ab Screening Assay \(Step 1\)](#)
- Attachment 3b Guidance for Reporting Results of the Recommended HIV Diagnostic Testing Algorithm to Providers and the NYSDOH – [Analyte Differentiating HIV Ag/Ab Screening Assay \(Step 1\)](#)
- Attachment 4 New York State Reportable HIV Related Tests

Questions regarding the updated laboratory guidelines for the HIV diagnostic testing may be directed to the NYSDOH by email to [hivtesting@health.ny.gov](mailto:hivtesting@health.ny.gov).

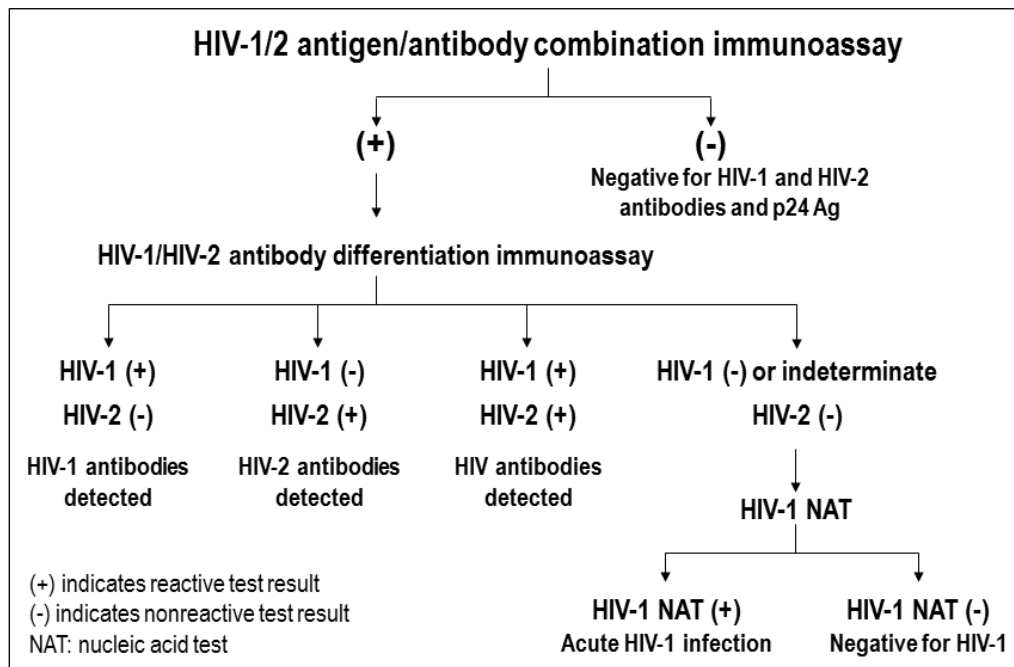
Questions regarding laboratory reporting of HIV-related test results should be directed to the Bureau of HIV/AIDS Epidemiology at 518-474-4284 or by email to [BHAELab@health.state.ny.us](mailto:BHAELab@health.state.ny.us).

Sincerely,

Stephanie H. Shulman, M.P.H., M.S., M.T. (ASCP)  
Director, Clinical Laboratory Evaluation Program  
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Monica M. Parker, Ph.D.  
Director, Bloodborne Viruses Laboratory  
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### Recommended Laboratory HIV Testing Algorithm for Serum or Plasma Specimens



1. Laboratories should conduct initial testing for HIV with an FDA-approved antigen/antibody combination immunoassay\* that detects HIV-1 and HIV-2 antibodies and HIV-1 p24 antigen to screen for established infection with HIV-1 or HIV-2 and for acute HIV-1 infection. No further testing is required for specimens that are nonreactive on the initial immunoassay.
2. Specimens with a reactive antigen/antibody combination immunoassay result (or repeatedly reactive, if repeat testing is recommended by the manufacturer or required by regulatory authorities) should be tested with an FDA-approved antibody immunoassay that differentiates HIV-1 antibodies from HIV-2 antibodies. Reactive results on the initial antigen/antibody combination immunoassay and the HIV-1/HIV-2 antibody differentiation immunoassay should be interpreted as positive for HIV-1 antibodies, HIV-2 antibodies, or HIV antibodies, undifferentiated.
3. Specimens that are reactive on the initial antigen/antibody combination immunoassay and nonreactive or indeterminate on the HIV-1/HIV-2 antibody differentiation immunoassay should be tested with an FDA-approved HIV-1 nucleic acid test (NAT).
  - A reactive HIV-1 NAT result and nonreactive HIV-1/HIV-2 antibody differentiation immunoassay result indicates laboratory evidence for acute HIV-1 infection.
  - A reactive HIV-1 NAT result and indeterminate HIV-1/HIV-2 antibody differentiation immunoassay result indicates the presence of HIV-1 infection confirmed by HIV-1 NAT.
  - A negative HIV-1 NAT result and nonreactive or indeterminate HIV-1/HIV-2 antibody differentiation immunoassay result indicates a false-positive result on the initial immunoassay.
4. Laboratories should use this same testing algorithm, beginning with an antigen/antibody combination immunoassay, with serum or plasma specimens submitted for testing after a reactive (preliminary positive) result from any rapid HIV test.

\* *Exception: As of April 2014, data are insufficient to recommend use of the FDA-approved single-use rapid HIV-1/HIV-2 antigen/antibody combination immunoassay as the initial assay in the algorithm.*

## FDA-Approved Test Methods Applicable to the HIV Diagnostic Testing Algorithm for Laboratories

This update takes into account new developments in HIV diagnostic testing that have occurred since May 16, 2013 when this test list was originally issued by the NYSDOH. On June 27, 2014, the Centers for Disease Control and Prevention (CDC) published updated recommendations for the diagnosis of HIV infection <http://www.cdc.gov/hiv/pdf/hivtestingalgorithmrecommendation-final.pdf>. In addition, several new tests intended for aiding the diagnosis of HIV infection have received approval from the Food and Drug Administration (FDA). As new updates to this document become available, they will be posted on NYSDOH website at <https://www.health.ny.gov/diseases/aids/providers/testing/loincs.htm>.

As of June 1, 2016, the following FDA-approved test kits are considered acceptable by the NYSDOH for use in the HIV Diagnostic Testing Algorithm for laboratories. Please see footnotes on the following page for additional details.

The Department's preferred LOINC codes for public health reporting of these tests in the Electronic Clinical Laboratory Reporting System (ECLRS) are listed. Please see Attachments 3 and 4 for additional guidance on requirements for laboratory reporting to the NYSDOH.

Test Kit Name	Test Manufacturer	Preferred LOINC and Result for ECLRS Reporting
<b><u>Step 1. HIV-1/HIV-2 Ag/Ab combo immunoassay (screening assay)<sup>1,2</sup></u></b>		
Abbott Architect HIV Ag/Ab Combo Assay	Abbott Laboratories	56888-1 Report <u>Reactive</u> results
GS HIV Ag/Ab Combo EIA	Bio-Rad Laboratories	56888-1 Report <u>Reactive</u> results
ADVIA Centaur HIV Ag/Ab Combo	Siemens HealthCare Diagnostics	56888-1 Report <u>Reactive</u> results
BioPlex 2200 HIV Ag-Ab assay	Bio-Rad Laboratories	56888-1 for HIV Ag-Ab; Report <u>Reactive</u> results <sup>6</sup> and 18396-2 for HIV-1 Ag; Report results and 29893-5 for HIV-1 Ab; Report results and 30361-0 for HIV-2 Ab; Report results
<b><u>Step 2. HIV-1/HIV-2 antibody differentiation immunoassay (supplemental antibody assay)<sup>3</sup></u></b>		
Multispot HIV-1/HIV-2 Rapid Immunoassay	Bio-Rad Laboratories	69668-2 Report <u>all</u> results
Geenius HIV 1/2 Supplemental Assay	Bio-Rad Laboratories	80203-3 Report <u>all</u> results
<b><u>Step 3. HIV nucleic acid test (supplemental RNA assay)<sup>4,5</sup></u></b>		
Aptima HIV-1 RNA Qualitative Assay	Hologic Gen-Probe	5018-7, 5017-9, 25835-0 Report <u>all</u> results

## Attachment 2

<sup>1</sup> **3<sup>rd</sup> Generation HIV-1/2 Immunoassays.** The CDC recommends that laboratories conduct initial testing with an FDA-approved HIV antigen/antibody (Ag/Ab) combo immunoassay (4th generation screening assay). 3rd generation (IgM/IgG antibody detecting) HIV-1/2 immunoassays are still available for screening but are not recommended for Step 1 because they do not detect p24 antigen and will miss some acute infections. **Laboratories that continue to screen with 3<sup>rd</sup> generation immunoassays should note this limitation on the provider report.** Furthermore, laboratories must use one of the laboratory-based HIV Ag/Ab immunoassays listed in the Table for Step 1 if they receive plasma or serum specimens for confirmation of a reactive rapid test. Use of a 3<sup>rd</sup> generation HIV-1/2 immunoassay in Step 1 could result in a false negative confirmatory result if a 4<sup>th</sup> generation HIV Ag/Ab combo rapid test was used for screening (see footnote 2).

<sup>2</sup> **HIV rapid tests including Alere Determine HIV-1/2 Ag/Ab Combo.** The Alere Determine HIV-1/2 Ag/Ab Combo assay is a 4<sup>th</sup> generation HIV Ag/Ab rapid test. As stated in the CDC's Updated Recommendations, data are insufficient to support its use in Step 1 of the Recommended HIV Laboratory Testing Algorithm. Therefore, the Alere Determine test should NOT be used in Step 1 of the algorithm until appropriate peer-reviewed data are available and updated recommendations have been issued. The Alere Determine assay and any of the other FDA-approved HIV rapid tests may be used as an initial screening test for HIV. A preliminary positive result on the Alere Determine assay or any other HIV rapid test requires confirmatory testing. Laboratories should begin rapid test confirmation by testing with one of the laboratory-based HIV Ag/Ab Combo immunoassays listed in the Table and follow the steps shown in the Recommended HIV Laboratory Testing Algorithm (Attachment 1).

<sup>3</sup> **Bio-Rad Laboratories has notified customers that the Multispot HIV-1/HIV-2 Rapid Immunoassay will be discontinued in July 2016. Labs may continue to use the Multispot test in Step 2 until supplies are depleted.**

<sup>4</sup> **HIV-1 RNA tests.** The currently available FDA-approved quantitative HIV-1 RNA tests (i.e. viral load tests) are not labeled for diagnostic use. Any modification to the manufacturer's instructions of an FDA-approved test, including a change to the manufacturer's stated intended use of the test, constitutes off-label use. Therefore, laboratories are restricted from using these quantitative HIV-1 RNA tests in Step 3 of the Diagnostic Testing Algorithm unless the laboratory has validated the test for diagnostic use and has received approval from the NYSDOH. For guidance on validating quantitative HIV-1 RNA tests for diagnostic use, contact [HIVtesting@health.ny.gov](mailto:HIVtesting@health.ny.gov). Laboratories that need assistance with qualitative HIV-1 RNA testing should contact the Wadsworth Center's Bloodborne Viruses Laboratory at (518) 474-2163.

<sup>5</sup> **HIV-2 RNA tests.** An HIV-2 nucleic acid test may be needed when the Geenius HIV-1/2 Supplemental Assay produces an HIV indeterminate or HIV-2 indeterminate result and the HIV-1 RNA assay is nonreactive. There are no FDA-approved HIV-2 RNA or DNA tests currently available for diagnostic use. A laboratory-developed HIV-2 RNA test that has been approved by the NYSDOH for diagnostic use is available at the NYSDOH Wadsworth Center. To determine if HIV-2 RNA testing is warranted, contact the Wadsworth Center's Bloodborne Viruses Laboratory at (518) 474-2163.

<sup>6</sup> When the BioPlex overall result (HIV Ag-Ab) is reactive, report the overall result as well as all results, reactive and nonreactive, for the individual analytes (HIV-1 p24 Ag, HIV-1 Ab and HIV-2 Ab).

**Guidance for Reporting Results of HIV Diagnostic Testing Algorithm to Providers and NYSDOH  
Non-Differentiating HIV Ag-Ab Screening Assay (Step 1)**

Step 1 HIV Ag-Ab Screening Assay	Step 2 HIV-1/2 Ab Differentiation Assay	Step 3 HIV-1 RNA Assay	Interpretation for Laboratory Report returned to Health Care Provider	Results reported to NYSDOH via ECLRS
NR	N/A	N/A	Negative for HIV-1 antigen and HIV-1/HIV-2 antibodies. No laboratory evidence of HIV infection.	NOT reportable
R	HIV-1 Pos	N/A	Positive for HIV-1 antibodies. Laboratory evidence of HIV-1 infection is present. <sup>1</sup>	Report all results
R	HIV-2 Pos <sup>4</sup>	N/A	Positive for HIV-2 antibodies. Laboratory evidence of HIV-2 infection is present. <sup>1,3</sup>	Report all results
R	NR or Any IND (HIV-1,HIV-2 or HIV) <sup>5</sup>	Detected <sup>2</sup>	Positive for HIV-1. Laboratory evidence consistent with acute or early HIV-1 infection is present. <sup>1</sup>	Report all results
R	NR or Any IND (HIV-1,HIV-2 or HIV) <sup>5</sup>	Not detected <sup>2</sup>	HIV antibodies were not confirmed and HIV-1 RNA was not detected. Possible false positive. Further testing is recommended if warranted by clinical evaluation or risk factors. <sup>3</sup>	Report all results
R	HIV Pos Untypable	N/A	Positive for HIV antibodies. Laboratory evidence of HIV infection is present. Antibodies not differentiated as HIV-1 or HIV-2. HIV-1 RNA and HIV-2 RNA or DNA testing is recommended. <sup>1,4</sup>	Report all results

**Abbreviations: Ag=antigen; Ab=antibody; R=reactive; NR=non-reactive; UR=unreportable HIV-1 Ag due to high HIV Ab level; R-UND=Reactive-Undifferentiated; Pos=Positive; IND=Indeterminate; N/A=not applicable**

<sup>1</sup> *Case reporting statement must appear on provider report.* Under public health law, within 14 days of diagnosis medical providers are required to report to the NYSDOH cases of HIV infection, HIV-related illness, AIDS and, for newly diagnosed cases, the names of all contacts known to the provider. Please contact the NYSDOH at (518) 474-4284 for additional information and reporting forms.

<sup>2</sup> If HIV-1 RNA assay was not performed or not reported due to invalid result, then algorithm results are inconclusive. The report should state that an HIV-1 RNA test should be ordered as soon as possible. Contact the NYSDOH Wadsworth Center Bloodborne Viruses Laboratory at (518) 474-2163 for assistance with HIV-1 RNA testing.

<sup>3</sup> Contact the NYSDOH Wadsworth Center Bloodborne Viruses Laboratory at (518) 474-2163 for assistance with HIV-2 nucleic acid testing.

<sup>4</sup> Includes both 'HIV-2 Positive' and 'HIV-2 Positive with HIV-1 Cross-Reactivity' results on the Geenius HIV-1/2 Supplemental Test.

<sup>5</sup> Studies have shown that the Geenius HIV-1/2 Supplemental test may produce an HIV-2 indeterminate result for specimens collected during acute HIV-1 infection. Therefore HIV-1 RNA testing is recommended when any indeterminate result occurs, regardless of HIV type.

**Guidance for Reporting Results of HIV Diagnostic Testing Algorithm to Providers and NYSDOH  
Differentiating HIV Ag-Ab Screening Assay (Step 1)**

Step 1 - Differentiating HIV Ag-Ab Screening Assay <sup>7</sup>				Step 2 HIV-1/2 Ab Differentiation Assay	Step 3 HIV-1 RNA Assay	Interpretation for Laboratory Report Returned to Health Care Provider	Results reported to NYSDOH via ECLRS
HIV Ag-Ab	HIV-1 Ag	HIV-1 Ab	HIV-2 Ab				
NR	NR	NR	NR	N/A	N/A	Negative for HIV-1 antigen and HIV-1/HIV-2 antibodies. No laboratory evidence of HIV infection.	NOT reportable
R	R	NR	NR	Not Done <sup>6</sup>	Detected <sup>2</sup>	Positive for HIV-1. Laboratory evidence consistent with acute HIV-1 infection is present. <sup>1</sup>	Report all results <sup>7</sup>
R	R	NR	NR	Not Done <sup>6</sup>	Not detected <sup>2</sup>	HIV-1 RNA was not detected. Possible false positive. Further testing is recommended if warranted by clinical evaluation or risk factors.	Report all results <sup>7</sup>
R	NR, R or UR	R R-UND	NR R-UND	HIV-1 Pos	N/A	Positive for HIV-1 antibodies. Laboratory evidence of HIV-1 infection is present. <sup>1</sup>	Report all results <sup>7</sup>
R	NR	NR R-UND	R R-UND	HIV-2 Pos <sup>4</sup>	N/A	Positive for HIV-2 antibodies. Laboratory evidence of HIV-2 infection is present. <sup>1,3</sup>	Report all results <sup>7</sup>
R	R or UR	NR R-UND	R R-UND	HIV-2 Pos <sup>4</sup>	Not detected <sup>2</sup>	Positive for HIV-2 antibodies. Laboratory evidence of HIV-2 infection is present. <sup>1,3</sup>	Report all results <sup>7</sup>
R	R or UR	NR R-UND	R R-UND	HIV-2 Pos <sup>4</sup>	Detected <sup>2</sup>	Positive for HIV-1 RNA and HIV-2 antibodies. Laboratory evidence is consistent with acute HIV-1 infection and HIV-2 infection; HIV-2 RNA or DNA testing is recommended to verify HIV-1/HIV-2 co-infection. <sup>1,3</sup>	Report all results <sup>7</sup>
R	NR, R or UR	R R-UND	NR R-UND	NR or Any IND (HIV-1,HIV-2 or HIV) <sup>5</sup>	Detected <sup>2</sup>	Positive for HIV-1. Laboratory evidence consistent with acute or early HIV-1 infection is present. <sup>1</sup>	Report all results <sup>7</sup>
R	NR, R or UR	R	NR	NR or HIV-1 IND	Not detected <sup>2</sup>	HIV antibodies were not confirmed and HIV-1 RNA was not detected. Possible false positive. Further testing is recommended if warranted by clinical evaluation or risk factors. <sup>3</sup>	Report all results <sup>7</sup>
R	NR, R or UR	NR R-UND	R R-UND	NR or Any IND (HIV-1,HIV-2 or HIV) <sup>5</sup>	Not detected <sup>2</sup>	HIV antibodies were not confirmed and HIV-1 RNA was not detected. Results are inconclusive. HIV-2 RNA or DNA testing is recommended. <sup>3</sup>	Report all results <sup>7</sup>
R	NR, R or UR	R R-UND NR	NR R-UND R	HIV Pos Untypable	N/A	Positive for HIV antibodies. Laboratory evidence of HIV infection is present. Antibodies not differentiated as HIV-1 or HIV-2. HIV-1 RNA and HIV-2 RNA or DNA testing is recommended. <sup>1,3</sup>	Report all results <sup>7</sup>

**Abbreviations: Ag=antigen; Ab=antibody; R=reactive; NR=non-reactive; UR=unreportable HIV-1 Ag due to high HIV Ab level; R-UND=Reactive-Undifferentiated; Pos=Positive; IND=Indeterminate; N/A=not applicable**

<sup>1</sup> *Case reporting statement must appear on provider report.* Under public health law, within 14 days of diagnosis medical providers are required to report to the NYSDOH cases of HIV infection, HIV-related illness, AIDS and, for newly diagnosed cases, the names of all contacts known to the provider. Please contact the NYSDOH at (518) 474-4284 for additional information and reporting forms.

<sup>2</sup> If HIV-1 RNA assay was not performed or not reported due to invalid result, then algorithm results are inconclusive. The report should state that an HIV-1 RNA test should be ordered as soon as possible. Contact the NYSDOH Wadsworth Center Bloodborne Viruses Laboratory at (518) 474-2163 for assistance with HIV-1 RNA testing.

<sup>3</sup> Contact the NYSDOH Wadsworth Center Bloodborne Viruses Laboratory at (518) 474-2163 for assistance with HIV-2 nucleic acid testing.

<sup>4</sup> Includes both 'HIV-2 Positive' and 'HIV-2 Positive with HIV-1 Cross-Reactivity' results on the Geenius HIV-1/2 Supplemental Test.

<sup>5</sup> Studies have shown that the Geenius HIV-1/2 Supplemental test may produce an HIV-2 indeterminate result for specimens collected during acute HIV-1 infection. Therefore HIV-1 RNA testing is recommended when any indeterminate result occurs, regardless of HIV type.

<sup>6</sup> According to CDC's current recommendations, a specimen that is reactive on a HIV Ag-Ab screening immunoassay should be tested with a supplemental HIV-1/HIV-2 antibody differentiation assay. However, if the HIV Ag-Ab screening immunoassay results indicate the specimen is reactive for HIV-1 antigen and nonreactive for HIV-1 and HIV-2 antibodies, the laboratory may opt to omit the supplemental antibody test step and perform the HIV-1 RNA test as the next step in the algorithm.

<sup>7</sup> When the differentiating HIV Ag-Ab screening result is reactive (R), report results of ALL individual analytes, including the HIV Ag-Ab, HIV-1 Ag, HIV-1 Ab, and HIV-2 Ab. In addition, report ALL results of supplemental testing performed on the specimen.

## **Guidance to Facilitate the Public Health Reporting of HIV-related Laboratory Test Results to New York State Department of Health (NYSDOH)**

### **New York State Reportable HIV Related Tests:**

Laboratories, blood and tissue banks conducting HIV-related testing on New York residents and/or for New York State clinicians (regardless of patient residence) are required by regulation to electronically report to the NYSDOH any laboratory test, tests or series of tests approved for the diagnosis of HIV or for the periodic monitoring of HIV infection with complete patient identifiers and address.

The following results or combination of results are to be reported to the NYSDOH via the Electronic Clinical Laboratory Reporting System (ECLRS):

- (1) All reactive/repeatedly reactive initial HIV immunoassay results AND all results (e.g. positive, negative, indeterminate) from all supplemental HIV immunoassays (HIV-1/2 antibody differentiation assay, HIV-1 Western blot, HIV-2 Western blot or HIV-1 Immunofluorescent assay)<sup>1</sup>;
- (2) All HIV nucleic acid (RNA or DNA) detection test results (qualitative and quantitative), including tests on individual specimens for confirmation of nucleic acid-based testing (NAT) screening results;
- (3) All CD4 lymphocyte counts and percentages, unless known to be ordered for a condition other than HIV;
- (4) HIV subtype and antiviral resistance. This reporting requirement should be met with the electronic submission of the protease, reverse transcriptase and integrase nucleotide sequence determined through genotypic resistance testing; and,
- (5) Positive HIV detection tests (culture, P24 antigen).

<sup>1</sup> Residuals from the original HIV-1 antibody positive diagnostic test specimen should be submitted for HIV incidence surveillance testing. Please contact the HIV Incidence Coordinator at (518) 474-4284 to arrange for specimen transfer.

All HIV-related laboratory reporting, including that for NYC residents or clinicians should be made directly to the NYSDOH, submitted electronically via ECLRS. Clinical laboratories are required to report results using patient identifying, demographic and locating information, as well as requesting provider information. For a complete list and instructions on how to report required data elements, please call 518-474-4284.

### **New York State HIV Data Elements:**

The federal funding available for care and monitoring of persons with HIV/AIDS is directly impacted by the surveillance case counts created by laboratory reports. CDC case confirmation and eligibility are dependent on the complete and accurate submission of the following variables in addition to the laboratory test result and ordering physician information that you submit.

For case confirmation, surveillance records must contain a known value for the following:

- Patient name
- Date of birth
- Sex assigned at birth
- Race and ethnicity<sup>2</sup>
- Patient residence at time of test

We appreciate your attention to the submission of these crucial identifying and demographic variables. If you are aware of specific providers or clients who are delinquent in providing you these critical variables for NYS reporting, please contact us for assistance. The ECLRS manual is a resource outlining a complete listing of all required, critical and preferred data elements and the appropriate formatting of each data element.

<sup>2</sup> NB: Race and ethnicity are distinct concepts and should be ascertained separately at intake and reported as distinct variables via ECLRS.



## OMB RACE AND ETHNICITY FEDERAL REPORTING GUIDELINES

### RACE AND ETHNICITY STANDARDS FOR FEDERAL STATISTICS AND ADMINISTRATIVE REPORTING (as adopted on May 12, 1977)

This Directive provides standard classifications for record keeping, collection, and presentation of data on race and ethnicity in Federal program administrative reporting and statistical activities.

The standards have five categories for data on race: American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, and White. There are two categories for data on ethnicity: "Hispanic or Latino," and "Not Hispanic or Latino."

#### Categories and Definitions

The minimum categories for data on race and ethnicity for Federal statistics, program administrative reporting, and civil rights compliance reporting are defined as follows:

#### Race:

- **American Indian or Alaska Native.** A person having origins in any of the original peoples of North and South America (including Central America), and who maintains tribal affiliation or community attachment. **Report to ECLRS as race=I<sup>3</sup>**
- **Asian.** A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam. **Report to ECLRS as race=A<sup>3</sup>**
- **Black or African American.** A person having origins in any of the black racial groups of Africa. Terms such as "Haitian" or "Negro" can be used in addition to "Black or African American." **Report to ECLRS as race=B<sup>3</sup>**
- **Native Hawaiian or Other Pacific Islander.** A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands. **Report to ECLRS as race=P<sup>3</sup>**
- **White.** A person having origins in any of the original peoples of Europe, the Middle East, or North Africa. **Report to ECLRS as race=W<sup>3</sup>**

#### Ethnicity:

- **Hispanic or Latino.** A person of Cuban, Mexican, Puerto Rican, Cuban, South or Central American, or other Spanish culture or origin, regardless of race. The term, "Spanish origin," can be used in addition to "Hispanic or Latino." **Report to ECLRS as ethnicity=H<sup>3</sup>**
- **Not Hispanic.** A person of not of Hispanic origin. **Report to ECLRS as ethnicity=N<sup>3</sup>**

Respondents shall be offered the option of selecting one or more racial designations. Recommended forms for the instruction accompanying the multiple response question are "Mark one or more" and "Select one or more."

For additional information, please see: [http://www.whitehouse.gov/omb/fedreg/directive\\_15.html](http://www.whitehouse.gov/omb/fedreg/directive_15.html)

<sup>3</sup> New York State Electronic Clinical Laboratory Reporting System (ECLRS). Use these codes if reporting to ECLRS via file transfer.