



Department of Health

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Executive Deputy Commissioner

March 14, 2018

Re: 2018 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 2016 Guidelines for Laboratories on the use of the Diagnostic Testing Algorithm for Human Immunodeficiency Virus (HIV) Infection issued by the New York State Department of Health on June 13, 2016. Since that date, the following developments have occurred.

- Additional HIV diagnostic tests have received approval from the Food and Drug Administration (FDA).
- The Geenius HIV-1/2 Supplement Assay (Bio-Rad Laboratories) became available and the Multispot HIV-1/HIV-2 Rapid Test has been discontinued. In addition, the FDA approved a revised package insert for the Geenius assay.
- The Centers for Disease Control and Prevention (CDC) published technical updates on [HIV-1/2 Differentiation Assays](#) (August 12, 2016) and the [Use of the Determine HIV-1/2 Ag/Ab Combo assay](#) (October 4, 2017).

The 2018 laboratory guidelines include the following updated attachments which have been posted on the NYSDOH website at <http://www.health.ny.gov/diseases/aids/providers/testing/index.htm>.

- Attachment 1 2018 Quick reference guide: Recommended laboratory HIV testing algorithm for serum or plasma specimens updated by the CDC January 2018
- 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.

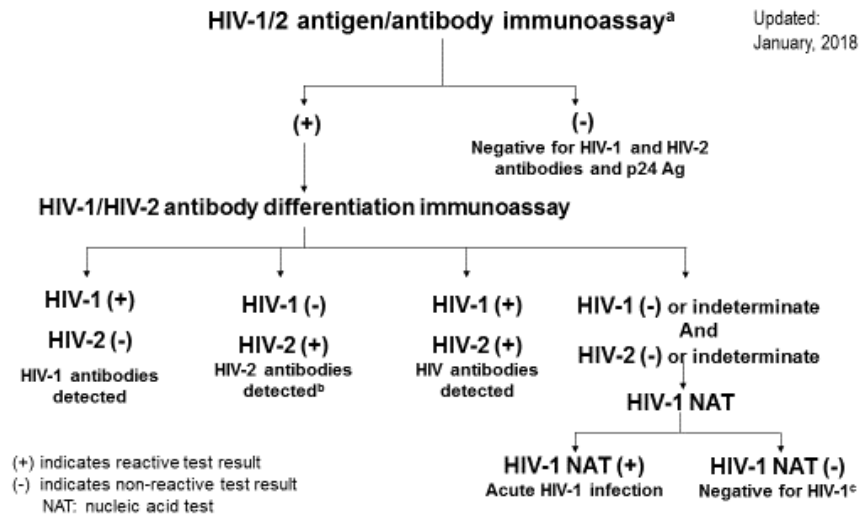
Questions regarding laboratory reporting of HIV-related test results should be directed to the Bureau of HIV/AIDS Epidemiology at 518-474-4284 or by email to BHAELab@health.ny.gov.

Sincerely,

Stephanie H. Shulman, M.P.H., M.S., M.T. (ASCP)
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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 immunoassay^a that detects HIV-1 and HIV-2 antibodies and HIV-1 p24 antigen to test for established HIV-1 and HIV-2 infection and for acute HIV-1 infection, respectively. No further testing is required for specimens that are non-reactive on the initial immunoassay. However, if there is a possibility of very early infection leading to a non-reactive initial antigen/antibody immunoassay, such as when recent HIV exposure is suspected or reported, then conduct an HIV-1 nucleic acid test (NAT), or request a new specimen and repeat the algorithm according to CDC guidance (1,4,5,6).
2. Specimens with a reactive antigen/antibody 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 supplemental antibody immunoassay that differentiates HIV-1 antibodies from HIV-2 antibodies. Reactive results on the initial antigen/antibody immunoassay and the HIV-1/HIV-2 antibody differentiation immunoassay should be interpreted as positive for HIV-1 antibodies, HIV-2 antibodies^b, or HIV antibodies, untypable (undifferentiated).
3. Specimens that are reactive on the initial antigen/antibody immunoassay and non-reactive or indeterminate on the HIV-1/HIV-2 antibody differentiation immunoassay should be tested with an FDA-approved HIV-1 NAT.
 - A reactive HIV-1 NAT result and non-reactive or indeterminate HIV-1/HIV-2 antibody differentiation immunoassay result indicates laboratory evidence of acute HIV-1 infection.
 - A negative HIV-1 NAT result and non-reactive or HIV-1 indeterminate antibody differentiation immunoassay result indicates an HIV-1 false-positive result on the initial immunoassay.
 - A negative HIV-1 NAT result and repeatedly HIV-2 indeterminate or HIV indeterminate antibody differentiation immunoassay result should be referred for testing with a different validated supplemental HIV-2 test (antibody test or NAT) or repeat the algorithm in 2 to 4 weeks, starting with an antigen/antibody immunoassay (3).
4. Laboratories should use this same testing algorithm, beginning with an antigen/antibody immunoassay on all serum or plasma specimens submitted for testing after a preliminary positive result from any rapid HIV test conducted in a CLIA-waived setting (7).

^aThe FDA-approved single-use rapid HIV-1/HIV-2 antigen/antibody immunoassay can be used as the initial assay in the laboratory HIV testing algorithm for serum or plasma. If any instrumented antigen/antibody test is available, it is preferred due to its superior sensitivity for detecting HIV during acute infection (1,2).

^bThis includes specimens reported as HIV-2 positive with HIV-1 cross-reactivity (3).

^cRefer to last bullet, item 3 above.

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

This update takes into account new tests that have been approved by the Food and Drug Administration (FDA) since the last NYSDOH update from June 13, 2016. In addition, the CDC issued a [Technical Update on the Use of the Determine HIV-1/2 Ag/Ab Combo assay](#) on October 4, 2017. The most recent document will be posted on the NYSDOH website at <https://www.health.ny.gov/diseases/aids/providers/testing/loincs.htm>.

As of February 15, 2018, 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 3a, 3b 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
<u>Step 1. HIV-1/HIV-2 Ag/Ab combo immunoassay (screening assay)</u> ^{1,2}		
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 ⁶ 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
Elecsys HIV combi PT	Roche Diagnostics	56888-1 Report <u>Reactive</u> results
VITROS HIV Combo	Ortho Clinical Diagnostics	56888-1 Report <u>Reactive</u> results
Determine HIV-1/2 Ag/Ab Combo ^{2,3} (Serum or plasma use only)	Alere	75666-8 Report <u>Reactive</u> results
<u>Step 2. HIV-1/HIV-2 antibody differentiation immunoassay (supplemental antibody assay)</u>		
Geenius HIV 1/2 Supplemental Assay	Bio-Rad Laboratories	80203-3 Report <u>all</u> Final Assay Interpretations If individual HIV-1 and HIV-2 results are also reported, use: 68961-2 for all HIV-1 results 81641-3 for all HIV-2 results
<u>Step 3. HIV nucleic acid test (supplemental RNA assay)</u> ^{4,5}		
Aptima HIV-1 RNA Qualitative Assay	Hologic Gen-Probe	5018-7, 5017-9, 25835-0 Report <u>all</u> results

¹ **Less sensitive 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). Less sensitive HIV screening assays that detect antibodies only are still available but are not recommended for use by laboratories because they do not detect p24 antigen and will miss some acute infections. These include HIV antibody screening assays that detect IgM and IgG antibodies (3rd generation) or IgG antibodies only (1st and 2nd generation). **Laboratories that screen with an assay other than a recommended HIV Ag/Ab immunoassay should include the statement “This screening assay may not detect acute HIV-1 infections” when reporting a negative screening result to the provider.**

² **Alere Determine HIV-1/2 Ag/Ab Combo.** The Alere Determine HIV-1/2 Ag/Ab Combo assay is a rapid test that detects HIV-1 p24 antigen and HIV-1/2 antibodies. The CDC’s Technical Update: Use of the Determine HIV 1/2 Ag/Ab combo test with serum or plasma in the laboratory algorithm for HIV diagnosis (<https://stacks.cdc.gov/view/cdc/48472>) continues to recommend that laboratories use an instrumented, laboratory-based HIV Ag/Ab screening immunoassay in Step 1 of the algorithm. However, for laboratories in which an instrumented Ag/Ab test is not feasible or practical, the Alere Determine HIV-1/2 Ag/Ab Combo assay may be used with serum or plasma for Step 1 in the laboratory algorithm. For any reactive result on the Alere Determine HIV-1/2 Ag/Ab Combo assay, the laboratory should proceed to Step 2, and then to Step 3 if needed.

³ **CLIA-waived rapid testing.** If any HIV rapid test, including the Alere Determine HIV-1/2 Ag/Ab Combo assay, produces a preliminary positive result in a CLIA-waived setting, confirmatory testing must be conducted by a clinical laboratory. Laboratories should begin rapid test confirmation by testing serum or plasma using one of the HIV Ag/Ab immunoassays listed for Step 1 and, if that test is reactive, follow the steps shown in the Recommended HIV Laboratory Testing Algorithm (Attachment 1). The Alere Determine HIV-1/2 Ag/Ab Combo assay may be used in Step 1 in this situation if it is the only HIV Ag/Ab test available in the laboratory.

⁴ **HIV-1 RNA testing.** 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 assistance with access to HIV-1 RNA testing or test validation, contact the Wadsworth Center’s Bloodborne Viruses Laboratory at (518) 474-2163 or HIVtesting@health.ny.gov.

⁵ **HIV-2 nucleic acid testing (NAT).** HIV-2 NAT may be needed when the Geenius HIV-1/2 Supplemental Assay produces a **Final Assay Interpretation** of HIV indeterminate or HIV-2 indeterminate and the HIV-1 RNA assay is nonreactive. There are no FDA-approved HIV-2 RNA or DNA tests currently available for diagnostic use. HIV-2 NAT approved by the NYSDOH for diagnostic use is available at the Wadsworth Center. To determine if HIV-2 NAT is warranted, contact the Wadsworth Center’s Bloodborne Viruses Laboratory at (518) 474-2163.

⁶ **Bioplex reporting.** 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 ¹	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. ²	Report all results
R	HIV-2 Pos ³	N/A	Positive for HIV-2 antibodies. Laboratory evidence of HIV-2 infection is present. ^{2,7}	Report all results
R	HIV Ab Neg or Any IND (HIV-1, HIV-2 or HIV)	Detected ^{4,5}	Positive for HIV-1. Laboratory evidence consistent with acute or early HIV-1 infection is present. ²	Report all results
R	HIV Ab Neg or Any IND (HIV-1, HIV-2 or HIV)	Not detected ^{4,5}	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. ^{6,7}	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 to verify or rule out HIV-1/HIV-2 dual infection. ^{2,7}	Report all results

Abbreviations: Ag=antigen; Ab=antibody; R=reactive; NR=non-reactive; Pos=Positive; Neg=Negative; IND=Indeterminate; N/A=not applicable

¹ Refers to Final Assay Interpretation of the Geenius HIV-1/2 Supplemental Assay. In September 2017, the FDA approved revisions to the Geenius package insert. The revised instructions for use state: **“The Final Assay Interpretation should always be reported to the ordering healthcare provider”**. Reporting of the individual HIV-1 and HIV-2 results to the provider is not recommended by the manufacturer and may lead to misinterpretation of the test results.

² *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. The Provider Report Form is now able to be completed electronically using the Provider Portal on the NYSDOH Health Commerce System at <https://commerce.health.ny.gov>. Please contact the NYSDOH at (518) 474-4284 for additional information.

³ Includes the Geenius Final Assay Interpretations ‘HIV-2 Positive’ and ‘HIV-2 Positive with HIV-1 Cross-Reactivity’.

⁴ If HIV-1 RNA assay was not performed or not reported due to an 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.

⁵ 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. <http://dx.doi.org/10.1016/j.jcv.2017.04.005>.

⁶ If the Geenius Final Assay Interpretation is 'HIV-2 indeterminate' or 'HIV indeterminate' and HIV-1 RNA was not detected, the report should instruct the provider to collect a new specimen in 2 to 4 weeks and repeat the algorithm. If a Geenius Final Assay Interpretation of 'HIV-2 indeterminate' or 'HIV indeterminate' persists upon repeat testing, an HIV-2 nucleic acid test (RNA or DNA) is recommended.

⁷ Refer providers to the NYSDOH Wadsworth Center Bloodborne Viruses Laboratory at (518) 474-2163 for assistance with HIV-1 or HIV-2 nucleic acid testing, including HIV-2 viral load testing for HIV-2 positive patients.

**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				Step 2 HIV-1/2 Ab Differentiation Assay ¹	Step 3 HIV-1 RNA Assay	Interpretation Language 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 positive for HIV antibodies ⁷	Detected ³	Positive for HIV-1. Laboratory evidence consistent with acute HIV-1 infection is present. ²	Report all results ⁸
R	R	NR	NR	Not positive for HIV antibodies ⁷	Not detected ³	HIV-1 RNA was not detected. Possible false positive. Further testing is recommended if warranted by clinical evaluation or risk factors.	Report all results ⁸
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. ²	Report all results ⁸
R	NR	NR R-UND	R R-UND	HIV-2 Pos ⁵	N/A	Positive for HIV-2 antibodies. Laboratory evidence of HIV-2 infection is present. ^{2,4}	Report all results ⁸
R	R or UR	NR R-UND	R R-UND	HIV-2 Pos ⁵	Not detected ³	Positive for HIV-2 antibodies. Laboratory evidence of HIV-2 infection is present. ^{2,4}	Report all results ⁸
R	R or UR	NR R-UND	R R-UND	HIV-2 Pos ⁵	Detected ³	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. ^{2,4}	Report all results ⁸
R	NR, R or UR	R R-UND	NR R-UND	NR or Any IND (HIV-1, HIV-2 or HIV) ⁶	Detected ³	Positive for HIV-1. Laboratory evidence consistent with acute or early HIV-1 infection is present. ²	Report all results ⁸
R	NR, R or UR	R	NR	NR or HIV-1 IND	Not detected ³	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. ⁴	Report all results ⁸
R	NR, R or UR	NR R-UND	R R-UND	NR or Any IND (HIV-1, HIV-2 or HIV) ⁶	Not detected ³	HIV antibodies were not confirmed and HIV-1 RNA was not detected. Results are inconclusive. HIV-2 RNA or DNA testing is recommended. ⁴	Report all results ⁸
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. ^{2,4}	Report all results ⁸

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

¹ Refers to Final Assay Interpretation of the Geenius HIV-1/2 Supplemental Assay. In September 2017, the FDA approved revisions to the Geenius package insert. The revised instructions for use state: **“The Final Assay Interpretation should always be reported to the ordering healthcare provider”**. Reporting of the individual HIV-1 and HIV-2 results to the provider is not recommended by the manufacturer and may lead to misinterpretation of the test results.

² *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. The Provider Report Form is now able to be completed electronically using the Provider Portal on the NYSDOH Health Commerce System at <https://commerce.health.ny.gov>. Please contact the NYSDOH at (518) 474-4284 for additional information.³ If HIV-1 RNA assay was not performed or not reported due to an 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.

⁴ Refer providers to the NYSDOH Wadsworth Center Bloodborne Viruses Laboratory at (518) 474-2163 for assistance with HIV-1 or HIV-2 nucleic acid testing, including HIV-2 viral load testing for HIV-2 positive patients.

⁵ Includes the Geenius Final Assay Interpretations ‘HIV-2 Positive’ and ‘HIV-2 Positive with HIV-1 Cross-Reactivity’.

⁶ 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. <http://dx.doi.org/10.1016/j.jcv.2017.04.005>.

⁷ The CDC’s current recommendations advise laboratories to conduct a supplemental HIV-1/HIV-2 antibody differentiation assay on all specimens that are reactive on a HIV Ag-Ab screening assay, but they do not address the situation in which a differentiating HIV Ag-Ab screening immunoassay produces a result that is reactive for HIV-1 antigen and nonreactive for HIV-1 and HIV-2 antibodies. The interpretation in this table is recommended by the NYSDOH if the laboratory performs a supplemental antibody assay and the result is not positive, or if the laboratory chooses to perform the HIV-1 RNA test as the second step in the algorithm in this situation (i.e. omitting the supplemental antibody assay).

⁸ 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);
- (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).

All HIV-related laboratory reporting, including that for NYC residents or NYC located clinicians, should be made directly to the NYSDOH, submitted electronically via ECLRS. Clinical laboratories are required to report results with patient identifying, demographic, and locating information, as well as the original ordering medical provider's full name, address and NPI. For reference laboratories, the original ordering medical provider's full name, address and NPI must be included. Referring laboratory name and address with CLIA and PFI should be reported as well. 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 ethnicity¹
- 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.

¹ 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=A²
- **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=A²
- **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=B²
- **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=P²
- **White.** A person having origins in any of the original peoples of Europe, the Middle East, or North Africa. Report to ECLRS as race=W²

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=H²
- **Not Hispanic.** A person of not of Hispanic origin. Report to ECLRS as ethnicity=N²

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: <https://www.gpo.gov/fdsys/pkg/FR-1997-10-30/pdf/97-28653.pdf>

² New York State Electronic Clinical Laboratory Reporting System (ECLRS). Use these codes if reporting to ECLRS via file transfer.