NEW YORK STATE OF OPPORTUNITY. Department of Health

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February 2024

Re: 2024 Guidelines Update 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 Permitted Clinical Laboratories performing diagnostic testing for human immunodeficiency virus (HIV). These updated documents supersede previous updates to the Guidelines for Laboratories on the use of the HIV Diagnostic Testing Algorithm issued by the New York State Department of Health in 2018 and 2021. The following developments are addressed.

- Additional HIV diagnostic nucleic acid tests and HIV-1/HIV-2 Ag/Ab immunoassays have received approval from the U.S. Food and Drug Administration (FDA).
- The Centers for Disease Control and Prevention (CDC) published the "Technical Update for HIV Nucleic Acid Tests Approved for Diagnostic Purposes" in May 2023.
- As of March 2023, NYS Public Health Law changes require clinician reporting of HIV laboratory test results obtained for the purpose of insurance underwriting. Laboratories must also report these results to the New York State Department of Health.

**The Guidelines for use of the HIV Diagnostic Testing Algorithm for Laboratories are posted on the New York State Department of Health website at http://www.health.ny.gov/diseases/aids/providers/testing/index.htm. The 2024 laboratory guidelines include the following new and updated attachments.**

- Attachment 1 Recommended Laboratory Human Immunodeficiency Virus (HIV) Diagnostic Testing Algorithm
- Attachment 2 FDA-approved Test Methods, Applicable to the HIV Diagnostic Testing Algorithm
- Attachment 3a Guidance for Reporting Results of HIV Diagnostic Testing Algorithm to Providers and the New York State Department of Health - Non-Differentiating HIV Ag-Ab Screening Assay (Step 1)
- Attachment 3b Guidance for Reporting Results of HIV Diagnostic Testing Algorithm to Providers and the New York State Department of Health - Differentiating HIV Ag-Ab Screening Assay (Step 1)
- Attachment 3c Guidance for Interpretation of HIV RNA Test Results for Diagnostic Purposes (Step 3)
- Attachment 4 Guidance to Facilitate the Public Health Reporting of HIV-related Laboratory Test Results to the New York State Department of Health

For questions regarding the updated laboratory guidelines for HIV diagnostic testing, email the New York State Department of Health at hivtesting@health.ny.gov.

For questions regarding laboratory reporting of HIV-related test results, contact the Bureau of HIV/AIDS Epidemiology at 518-474-4284 or BHAELab@health.ny.gov.

Sincerely,

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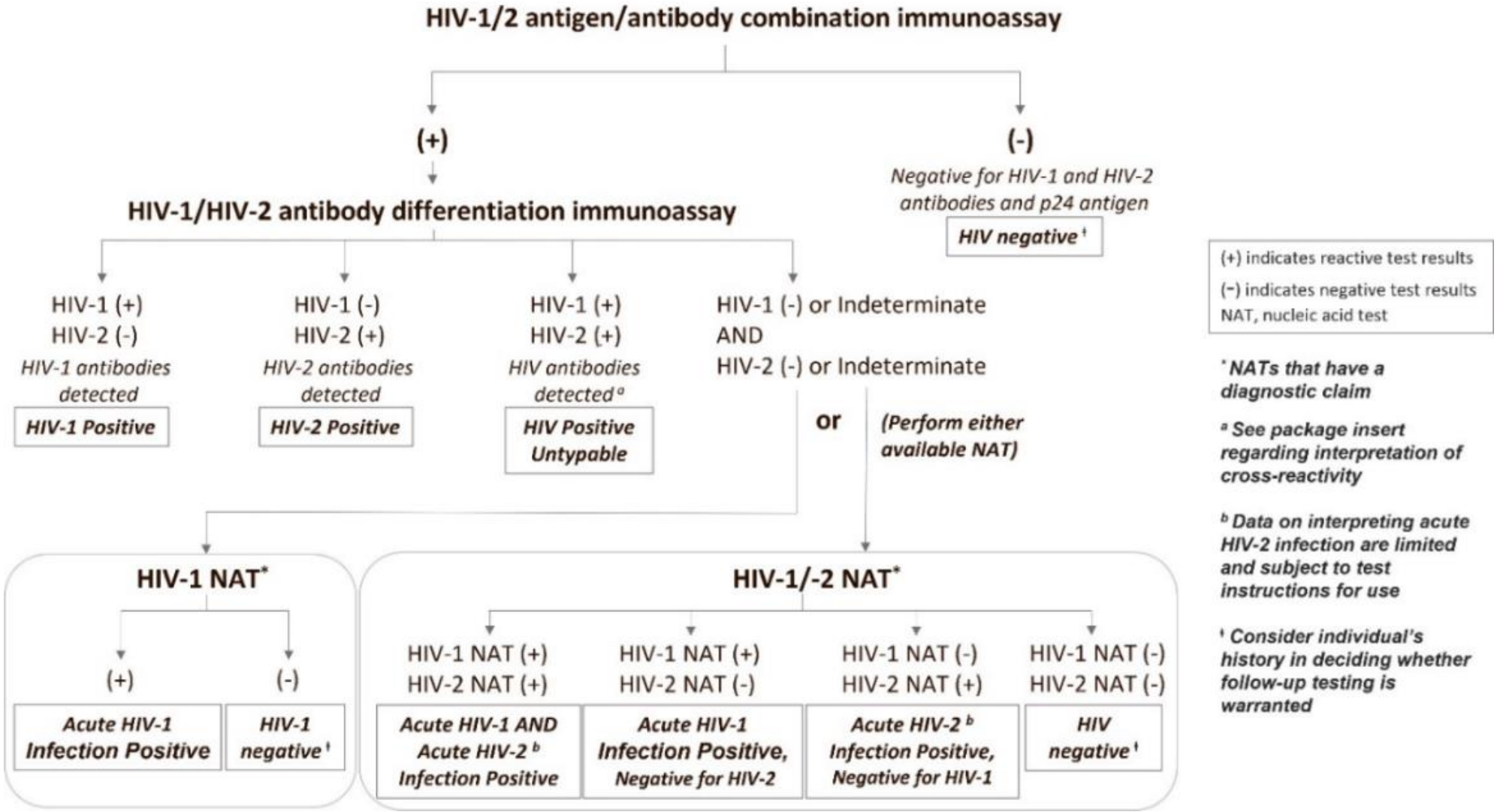
# Recommended Laboratory Human Immunodeficiency Virus (HIV) Diagnostic Testing Algorithm




This figure shows the current recommended laboratory *HIV diagnostic testing algorithm* (1). The algorithm was updated to include approved HIV-1 and HIV-1/-2 nucleic acid tests with a diagnostic claim for step 3. See (1) for information on alternate, but not recommended, algorithms.

1. Laboratories should conduct initial testing for HIV with a U.S. Food and Drug Administration (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 or HIV-1/-2 Nucleic Acid Test (NAT) or request a new specimen and repeat the algorithm according to CDC guidance (2, 3, 4, 5).
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 or HIV-1/-2 NAT.
    - A reactive HIV-1 or HIV-2 NAT result and non-reactive or indeterminate HIV-1/HIV-2 antibody differentiation immunoassay result indicates laboratory evidence of acute HIV-1 or HIV-2 infection, respectively.
    - A negative HIV-1 or HIV-1/-2 NAT result and non-reactive or indeterminate HIV-1/HIV-2 antibody differentiation immunoassay result could indicate a false-positive result on the initial immunoassay or could occur in individuals using pre-exposure prophylaxis (PrEP), or who were treated early in infection with antiretroviral therapy, which can lead to low virus levels and delay or inhibit seroconversion.
    - 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 (6). Samples with a negative HIV-1/-2 NAT result do not need additional HIV-2 testing.
4. Laboratories should use the 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).

[a] The 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 (2, 8).
[b] This includes specimens reported as HIV-2 positive with HIV-1 cross-reactivity (6).

(1) Technical Update for HIV Nucleic Acid Tests Approved for Diagnostic Purposes. https://stacks.cdc.gov/view/cdc/129018
(2) Laboratory Testing for the Diagnosis of HIV Infection: Updated Recommendations https://stacks.cdc.gov/view/cdc/23447
(3) APHL Suggested Reporting Language for the HIV Laboratory Diagnostic Testing Algorithm https://stacks.cdc.gov/view/cdc/79272
(4) Updated Guidelines for Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV-United States, 2016 https://stacks.cdc.gov/view/cdc/38856
(5) HIV Testing https://www.cdc.gov/hiv/testing/
(6) Technical Update on HIV-1/2 Differentiation Assays https://stacks.cdc.gov/view/cdc/40790
(7) Clinical Laboratory Improvement Amendments https://www.cdc.gov/clia/
(8) 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

# Food and Drug Administration-Approved Test Methods, Applicable to the HIV Diagnostic Testing Algorithm for Laboratories

As of January 1, 2024, the following United States Food and Drug Administration (FDA)-approved tests are available for use in the HIV Diagnostic Testing Algorithm for laboratories. The New York State Department of Health's preferred Logical Observation Identifiers Name and Codes (LOINC) for public health reporting in the Electronic Clinical Laboratory Reporting System (ECLRS) are listed.

| Test Kit Name | Instrument Platform(s) | Test Manufacturer | Preferred LOINC and Result for ECLRS Reporting |
|---|---|---|---|
| **Step 1. HIV-1/HIV-2 Ag/Ab combo immunoassay (screening assay)[1,2]** | | | |
| HIV Ag/Ab Combo | Architect, Alinity | Abbott Laboratories | 56888-1; Report Reactive results |
| Determine HIV-1/2 Ag/Ab Combo (Serum or plasma use only) | Not Applicable | Abbott Laboratories | 75666-8; Report Antibody Reactive results<br>or Antigen Reactive results<br>or Antibody Reactive and Antigen Reactive results |
| Access HIV Ag/Ab Combo | DxI 9000 | Beckman Coulter | 56888-1; Report Reactive results |
| GS HIV Ag/Ab Combo EIA | Open, Evolis | Bio-Rad Laboratories | 56888-1; Report Reactive results |
| BioPlex 2200 HIV Ag-Ab | BioPlex 2200 | Bio-Rad Laboratories | 56888-1 for HIV Ag-Ab; Report Reactive results[3]<br>and 18396-2 for HIV-1 Ag; Report results<br>and 29893-5 for HIV-1 Ab; Report results<br>and 30361-0 for HIV-2 Ab; Report results |
| LIAISON XL Murex HIV Ab/Ag HT | LIAISON XL | DiaSorin | 56888-1; Report Reactive results |
| HIV Combo | Vitros, ECi/ECiQ, 3600, 5600, XT 7600 | Ortho Clinical Diagnostics | 56888-1; Report Reactive results |
| Elecsys HIV combi PT | Cobas e602 | Roche Diagnostics | 56888-1; Report Reactive results |
| Elecsys HIV Duo | Cobas e801 | Roche Diagnostics | 56888-1 Report Reactive for HIV Ab and HIV-1 Ag[4]<br>OR |
| | Cobas e402 | | 56888-1 Report Reactive for HIV Ab and HIV-1 Ag[4]<br>and 31201-7 Report HIV1+2 Ab; Report results<br>and 18396-2 Report HIV-1 p24 Ag; Report results |
| HIV Ag/Ab Combo (CHIV) | ADVIA Centaur, Atellica | Siemens Medical Solutions | 56888-1; Report Reactive results |

| Test Kit Name | Instrument Platform(s) | Test Manufacturer | Preferred LOINC and Result for ECLRS Reporting |
|---|---|---|---|
| **Step 2. HIV-1/HIV-2 antibody differentiation immunoassay (supplemental antibody assay)** | | | |
| VioOne HIV Profile Supplemental Assay | Open | Avioq | 95524-5 Report all result interpretations<br>If individual HIV-1 and HIV-2 results are also reported, use:<br>29893-5 for all HIV-1 Ab results<br>30361-0 for all HIV-2 Ab results |
| Geenius HIV 1/2 Supplemental Assay | Geenius Reader | Bio-Rad Laboratories | 80203-3 Report all final assay interpretations<br>If individual HIV-1 and HIV-2 results are also reported, use:<br>68961-2 for all HIV-1 results<br>81641-3 for all HIV-2 results |
| **Step 3. HIV nucleic acid test (supplemental RNA assay)** | | | |
| Aptima HIV-1 Quant Dx Assay<br>(Quantitative results: Plasma only)<br>(Qualitative results: Plasma & serum) | Panther | Hologic | 25835-0 Report all qualitative results<br>20447-9 Report all quantitative HIV-1 RNA copies/mL results<br>29541-0 Report all quantitative HIV 1 RNA $Log_{10}$ results |
| Alinity m HIV-1 Assay<br>(Quantitative Results: Plasma only)<br>(Qualitative results: Plasma & serum) | Alinity m | Abbott Molecular | 25835-0 Report all qualitative results<br>20447-9 Report all quantitative HIV-1 RNA copies/mL results<br>29541-0 Report all quantitative HIV 1 RNA $Log_{10}$ results |
| cobas HIV-1/HIV-2 Qualitative Assay | Cobas 6800, 8800 | Roche Diagnostics | 96556-6 Report all results<br>25835-0 Report for all HIV-1 RNA results<br>69353-1 Report for all HIV-2 RNA results |

[1] **Recommended Screening Immunoassays.** The CDC recommends that laboratories conduct initial testing with an FDA-approved HIV antigen/antibody (Ag/Ab) immunoassay. Less sensitive antibody-only assays are available but are not recommended**. Laboratories that use an antibody-only assay should include the following statement when reporting a negative screening result, "This screening assay may not detect acute HIV-1 infections."**

[2] **Determine HIV-1/2 Ag/Ab Combo.** 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) recommends 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 Determine HIV-1/2 Ag/Ab Combo assay may be used with serum or plasma for Step 1 in the laboratory algorithm.

[3] **BioPlex 2200 HIV Ag-Ab Assay.** 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).

[4] **Elecsys HIV Duo.** When the Elecsys Duo overall result (HIV Ab and HIV-1 Ag) is reactive, report all available results i.e., overall result and (if possible) reactive and nonreactive results for the individual analytes (HIV1+2 Ab and HIV-1 p24 Ag).

# Guidance for Reporting Results of HIV Diagnostic Testing Algorithm to Providers and the New York State Department of Health

## Non-Differentiating HIV Ag/Ab Screening Assay (Step 1)

| Step 1 HIVAg/Ab Assay | Step 2 HIV-1/HIV-2 Ab Differentiation Assay[1] | Step 3 HIV-1 or HIV-1/-2 RNA | Interpretation for Laboratory Report returned to Health Care Provider | Results reported to the New York State Department of Health |
|---|---|---|---|---|
| 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 Pos Untypable | N/A | Positive for HIV-1 and HIV-2 antibodies. Laboratory evidence of HIV-1 and/or HIV-2 infection is present. HIV-1 NAT and HIV-2 NAT are recommended to verify or rule out HIV-1/HIV-2 dual infection.[2,7] | Report all results |
| R | HIV Ab Neg or Any IND (HIV-1, HIV-2 or HIV) | HIV-1 RNA Detected[4,5] | Positive for HIV-1. Laboratory evidence of HIV-1 infection consistent with an acute HIV-1 infection.[2] | Report all results |
| R | HIV Ab Neg or Any IND (HIV-1, HIV-2 or HIV) | HIV-1 RNA Not Detected, HIV-2 RNA Detected[4,5] | Positive for HIV-2. Laboratory evidence of HIV-2 infection consistent with an acute HIV-2 infection.[2] | Report all results |
| R | HIV Ab Neg or Any IND (HIV-1, HIV-2 or HIV) | Not Detected[4,5] | HIV-1 antibodies were not confirmed and HIV-1 RNA (or HIV-1 and HIV-2 RNA) was not detected. Possible false positive. Further testing is recommended if warranted by clinical evaluation or risk factors.[6,7] | Report all results |

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

1 Refers to Final Assay Interpretation of the Geenius HIV-1/2 and Results Interpretation of the VioOne HIV Profile Supplemental Assays. Reporting of the individual HIV-1 and HIV-2 results to the provider is not recommended and may lead to misinterpretation of the test results.

2 *Laboratory Report returned to Health Care provider*: Under public health law, within one day (24 hours) of diagnosis or determination of acute HIV infection and seven days of a positive laboratory result or after diagnosis, medical providers are required to report to the New York State Department of Health 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 New York State Department of Health' Health Commerce System at https://commerce.health.ny.gov. Please contact the New York State Department of Health 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' and VioOne HIV Profile Interpretations 'HIV-2 Positive' and 'HIV-2 Positive with Reactivity to HIV-1 Antigens'.

4 If HIV-1 or HIV-1/-2 RNA assays were not performed or not reported due to an invalid result, then algorithm results are inconclusive. The report should state that an HIV-1 or HIV-1/-2 RNA test should be ordered as soon as possible. Contact the New York State Department of Health Wadsworth Center Bloodborne Viruses Laboratory at (518) 474-2163 for assistance with HIV-1 and HIV-2 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 NAT is recommended.

7 Refer providers to the New York State Department of Health Wadsworth Center Bloodborne Viruses Laboratory at (518) 474-2163 for assistance with HIV-1 or HIV-2 NAT, including viral load testing for HIV-2 positive patients.

# Guidance for Reporting Results of HIV Diagnostic Testing Algorithm to Providers and the New York State Department of Health

## Differentiating HIV Ag-Ab Screening Assay (Step 1)

| Step 1 - Differentiating HIV Ag-Ab Screening Assay | | | | Step 2 HIV-1/HIV-2 Ab Differentiation Assay[1] | Step 3 HIV-1 or HIV-1/-2 RNA Assay | Interpretation Language for Laboratory Report Returned to Health Care Provider[8] | Results reported to the NYSDOH |
|---|---|---|---|---|---|---|---|
| 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] | HIV-1 RNA Detected[3] | Positive for HIV-1. Laboratory evidence of HIV-1 infection consistent with an acute HIV-1 infection.[2] | Report all results[9] |
| R | R | NR | NR | Not positive for HIV antibodies[7] | HIV-1 RNA Not detected[3] | 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[9] |
| R | NR, R or UR | R | NR | HIV-1 Pos | N/A | Positive for HIV-1 antibodies. Laboratory evidence of HIV-1 infection is present.[2] | Report all results[9] |
| | | R-UND | R-UND | | | | |
| R | NR | NR | R | HIV-2 Pos[5] | N/A | Positive for HIV-2 antibodies. Laboratory evidence of HIV-2 infection is present.[2,4] | Report all results[9] |
| | | R-UND | R-UND | | | | |
| R | R or UR | NR | R | HIV-2 Pos[5] | HIV-1 RNA Not detected[3] | Positive for HIV-2 antibodies. Laboratory evidence of HIV-2 infection is present.[2,4] | Report all results[9] |
| | | R-UND | R-UND | | | | |
| R | R or UR | NR | R | HIV-2 Pos[5] | HIV-1 RNA 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[9] |
| | | R-UND | R-UND | | | | |
| R | NR, R or UR | R | NR | NR or Any IND (HIV-1, HIV-2 or HIV)[6] | HIV-1 RNA Detected[3] | Positive for HIV-1. Laboratory evidence of HIV-1 infection consistent with an acute or early HIV-1 infection.[2] | Report all results[9] |
| | | R-UND | R-UND | | | | |
| R | NR, R or UR | R | NR | NR or HIV-1 IND | HIV-1 RNA 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[9] |
| R | NR, R or UR | NR | R | HIV-2 or HIV IND[6] | HIV-1 RNA Not detected, HIV-2 RNA Detected[3] | Positive for HIV-2. Laboratory evidence of HIV-2 infection consistent with an early HIV-2 infection.[2] | Report all results[9] |
| | | R-UND | R-UND | | | | |
| R | NR, R or UR | NR | R | NR or Any IND (HIV-1, HIV-2 or HIV)[6] | HIV-1 RNA 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[9] |
| | | R-UND | R-UND | | | | |
| R | NR, R or UR | R | NR | HIV Pos Untypable | N/A | Positive for HIV-1 and HIV-2 antibodies. Laboratory evidence of HIV-1 and/or HIV-2 infection is present. HIV-1 NAT and HIV-2 NAT are recommended to verify or rule out HIV-1/HIV-2 dual infection.[2,4] | Report all results[9] |
| | | R-UND | R-UND | | | | |
| | | NR | R | | | | |

**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; NAT= nucleic acid testing; NYSDOH = New York State Department of Health**

[1] Refers to Final Assay Interpretation of the Geenius HIV-1/2 and Results Interpretation of the VioOne HIV Profile Supplemental Assays. 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] *Laboratory Report returned to Health Care provider*: Under public health law, within one day (24 hours) of diagnosis or determination of acute HIV infection and seven days of a positive laboratory result or after diagnosis, medical providers are required to report to the New York State Department of Health 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 New York State Department of Health' Health Commerce System at https://commerce.health.ny.gov. Please contact the New York State Department of Health at (518) 474-4284 for additional information.

[3] If HIV-1 or HIV-1/-2 RNA assays were not performed or not reported due to an invalid result, then algorithm results are inconclusive. The report should state that an HIV-1 or HIV-1/-2 RNA test should be ordered as soon as possible. Contact the New York State Department of Health Wadsworth Center Bloodborne Viruses Laboratory at (518) 474-2163 for assistance with HIV-1 and HIV-2 RNA testing.

[4] Refer providers to the New York State Department of Health Wadsworth Center Bloodborne Viruses Laboratory at (518) 474-2163 for assistance with HIV-1 or HIV-2 NAT, 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' and VioOne HIV Profile Interpretations 'HIV-2 Positive' and 'HIV-2 Positive with Reactivity to HIV-1 Antigens'.

[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 New York State Department of Health 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] For differentiating HIV Ag-Ab screening assay, the laboratory reports returned to health care provider must indicate ALL available individual analytes, including the HIV Ag-Ab, HIV-1 Ag, HIV-1 Ab, and HIV-2 Ab.

[9] When the differentiating HIV Ag-Ab screening result is reactive (R), report results of ALL available individual analytes to the New York State Department of Health, 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 for Interpretation of HIV RNA Test Results for Diagnostic Purposes (Step 3)

Three HIV nucleic acid tests (NATs) are approved by the United States Food and Drug Administration (FDA) for diagnostic use. This document provides guidance on the use of these HIV NATs in the third step of the current HIV Diagnostic Testing Algorithm. See https://www.cdc.gov/hiv/guidelines/recommendations/technical-update-for-hiv.html for additional guidance on the results and interpretations of the nucleic acid tests used for diagnostic purposes.

## A. Cobas HIV-1/HIV-2 Qualitative Test (Serum and Plasma)

The HIV-1/HIV-2 Qualitative test is presently the only FDA-approved qualitative NAT that provides and differentiates results for HIV-1 and HIV-2; this includes an overall result, individual results for HIV-1 and HIV-2, and a result interpretation for serum and plasma. Possible valid result combinations for the HIV-1/HIV-2 Qualitative test and interpretation are represented in the following table:

| Target Results | Overall Result | Interpretation |
|---|---|---|
| HIV-1 reactive and HIV-2 reactive. | Reactive | Target signal detected for HIV-1 and HIV-2. |
| HIV-1 reactive and HIV-2 non-reactive. | Reactive | Target signal detected for HIV-1.<br>No target signal detected for HIV-2. |
| HIV-1 non-reactive and HIV-2 reactive. | Reactive | No target signal detected for HIV-1.<br>Target signal detected for HIV-2. |
| HIV-1 non-reactive and HIV-2 non-reactive. | Non-Reactive | No target signal detected for HIV-1 or HIV-2. |

## B. Aptima HIV-1 Quant Dx Assay (Serum and Plasma)

| Result (copies/mL)* | Interpretation | Confirmatory Interpretation |
|---|---|---|
| Not detected** | Target not detected | Non-reactive for HIV-1 RNA |
| <30 | Detected <30 | Reactive for HIV-1 RNA |
| 30 to 10,000,000 | Detected and quantified | Reactive for HIV-1 RNA |
| >10,000,000 | >10,000,000 | Reactive for HIV-1 RNA |

*Quantitative results can be reported on plasma samples only.
** A "Not detected" result should not be reported with a numerical value (*e.g.*, <30) to avoid confusion in conveying the absence or presence of detectable HIV-1 RNA.

## C. Alinity m HIV-1 Assay

*C.1.Plasma*
For plasma samples, laboratories should interpret the HIV-1 RNA concentration as a qualitative result by following the 'User's Diagnostic Qualitative Interpretation' in the instructions for use, summarized in the below table.

| Result (copies/mL) | Interpretation | Confirmatory Interpretation |
|---|---|---|
| Not detected* | Target not detected | Negative |
| <20 | Detected <20 | Positive |
| 20 to 10,000,000 | Detected and quantified | Positive |
| >10,000,000 | >10,000,000 | Positive |

* A "Not detected" result should not be reported with a numerical value (*e.g.*, <20) to avoid confusion in conveying the absence or presence of detectable HIV-1 RNA.

*C.2. Serum*
For serum samples, quantitative results are not reported. Instead, only the qualitative results are reported as summarized in the table below.

| Result | Interpretation |
|---|---|
| HIV-1 RNA not detected | Negative |
| HIV-1 RNA detected | Positive |

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

## 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 New York State Department of Health 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 New York State Department of Health 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 New York City residents or New York City located clinicians, should be made directly to the New York State Department of Health, 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 National Provider Identifier (NPI). For reference laboratories, the original ordering medical provider's full name, address, and NPI must be included. Referring laboratory name and address with the Clinical Laboratory Improvement Amendments (CLIA) number and the Permanent Facility Identifier (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 ethnicity[1]
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] 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 seven categories for data on race: American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, White, Other, and Unknown. 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 or Logical Observation Identifiers Name and Codes (LOINC)=1002-5.[2]
- **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 or LOINC=2028-9. [2]
- **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 or LOINC=2054-5. [2]
- **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 or LOINC=2076-8.[2]
- **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 or LOINC=2106-3. [2]
- **Other.** A person whose origins are not described above. Report to ECLRS as race=O or LOINC=2131-1. [2]
- **Unknown.** A person whose racial information is not available. Report to ECLRS as race=U.[2] LOINC is not available for this category.

**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 or LOINC=2135-2. [2]
- **Not Hispanic.** A person of not of Hispanic origin. Report to ECLRS as ethnicity=N or LOINC=2186-5. [2]

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."

[2] Use these codes if reporting to ECLRS via file transfer. For additional information, please see the Office of Budget and Management, Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity