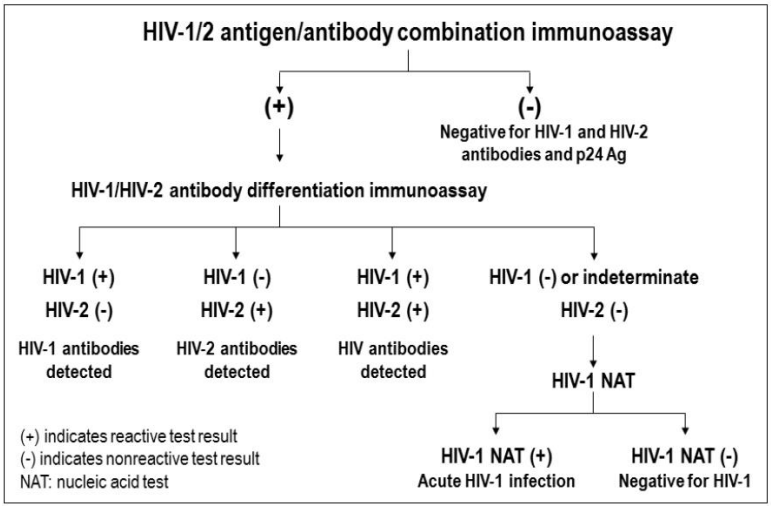
Overview

All diagnostic HIV test results are reportable to the Ohio Department of Health (ODH), including initial reactive screening results and the corresponding supplemental or confirmatory test result. Additionally, **ALL** results of HIV prognostic tests (e.g., CD4+T-Lymphocyte count and percentage tests and HIV-1 quantitative viral load tests) are reportable. HIV test results are to be reported electronically. ELR onboarding information can be found here. Please complete the ODH HIV laboratory test survey https://redcap.link/ODH_HIV_Lab_Test.

Laboratories should refer to the Centers for Disease Control and Prevention (CDC) Recommended Laboratory HIV Testing Algorithm for Serum or Plasma Specimens for guidance on a multi-step algorithm for the detection of HIV.



- Laboratories should conduct initial (screening) 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 test for established HIV-1 or HIV-2 infection and for acute HIV-1 infection. No further testing is required for specimens that are nonreactive on the initial (screening) immunoassay.
- Specimens with a reactive initial (screening) result should be tested with an FDA-approved supplemental/confirmatory antibody immunoassay that differentiates HIV-1 antibodies from HIV-2 antibodies.
- Specimens that are reactive on the initial (screening) antigen/antibody combination immunoassay and nonreactive or indeterminate on the HIV-1/HIV-2 antibody supplemental/confirmatory differentiation immunoassay should be tested with an FDA-approved HIV-1 nucleic acid test (NAT), preferably a qualitative NAT that tests for both HIV-1 and HIV-2.

Common HIV screening tests and how to report

***Note:** Laboratories should filter to send reactive screening results ONLY IF the supplemental/confirmatory test is also positive (i.e., NOT Negative or Indeterminate). If filtering is not possible, then ALL corresponding supplemental/confirmatory results should be reported, regardless of result, when a screening result is reactive.

Bio-Rad GS HIV Combo Ag/Ab EIA

The Bio-Rad GS HIV Combo Ag/Ab EIA (LOINC = 56888-1) tests for antibodies to HIV-1/2.

If reactive, report as one OBX segment:

> OBX|1|CWE|56888-1^HIV 1+2 Ab+HIV1 p24 Ag Ser Ql EIA^LN^1235000647^BKR HIV-1/HIV-2 AB WITH P24 ANTIGEN^LABRSLTOUT^2.44||11214006^Reactive^SCT…

Alere Determine HIV-1/2 Ag/Ab Combo Test

The Alere Determine HIV-1/2 Ag/Ab Combo Test (LOINC = 75666-8) tests for antibodies to HIV-1/2 and the HIV-1 p24 antigen.

If the antibody analyte is positive (and antigen is negative), report as one OBX segment:

> OBX|1|CWE|75666-8^HIV 1+2 Ab+HIV1p24 Ag SerPlBld IA.rapid^LN^1740042^RAPID HIV 1 AND 2^L||259855002^Human immunodeficiency virus antibody^SCT…

If the antigen analyte is positive (and antibody is negative), report as one OBX segment:

> OBX|1|CWE|75666-8^HIV 1+2 Ab+HIV1p24 Ag SerPlBld IA.rapid^LN^1740042^RAPID HIV 1 AND 2^L||713008009^Human immunodeficiency virus p24 antigen positive^SCT…

If both the antibody and the antigen analyte are positive, report as two OBX segments using the same LOINC:

> OBX|1|CWE|75666-8^HIV 1+2 Ab+HIV1p24 Ag SerPlBld IA.rapid^LN^1740042^RAPID HIV 1 AND 2^L||259855002^Human immunodeficiency virus antibody^SCT…
>
> OBX|2|CWE|75666-8^HIV 1+2 Ab+HIV1p24 Ag SerPlBld IA.rapid^LN^1740042^RAPID HIV 1 AND 2^L||713008009^Human immunodeficiency virus p24 antigen positive^SCT…

If reporting analytes separately is not possible, report as one OBX segment:

> OBX|1|CWE|75666-8^HIV 1+2 Ab+HIV1p24 Ag SerPlBld IA.rapid^LN^1740042^RAPID HIV 1 AND 2^L||11214006^REACTIVE^SCT…

Common HIV supplemental/confirmatory tests and how to report

Bio-Rad Geenius HIV 1/2 Supplemental System

HIV-1 analyte result is: (LOINC = 68961-2)	HIV-2 analyte result is: (LOINC = 81641-3)	Overall Differentiation Interpretation is: (LOINC = 80203-3)
Positive [10828004^Positive^SCT]	**Positive** [10828004^Positive^SCT]	**HIV Positive Untypable** [713742005^Human immunodeficiency virus antibody positive^SCT]
Positive [10828004^Positive^SCT]	**Negative** [260385009^Negative^SCT]	**HIV-1 Positive** [89293008^Human immunodeficiency virus type 1^SCT]
Positive [10828004^Positive^SCT]	**Indeterminate** [82334004^Indeterminate^SCT]	**HIV-1 Positive** [89293008^Human immunodeficiency virus type 1^SCT]
Negative [260385009^Negative^SCT]	**Positive** [10828004^Positive^SCT]	**HIV-2 Positive** [36115006^Human immunodeficiency virus type 2^SCT]
Negative [260385009^Negative^SCT]	**Negative** [260385009^Negative^SCT]	**HIV Negative** [260385009^Negative^SCT]
Negative [260385009^Negative^SCT]	**Indeterminate** [82334004^Indeterminate^SCT]	**HIV-2 Indeterminate** [719767004^Human immunodeficiency virus 2 antibody indeterminate^SCT]
Indeterminate [82334004^Indeterminate^SCT]	**Positive** [10828004^Positive^SCT]	**HIV-2 Positive** [36115006^Human immunodeficiency virus type 2^SCT]
Indeterminate [82334004^Indeterminate^SCT]	**Negative** [260385009^Negative^SCT]	**HIV-1 Indeterminate** [719727000^Human immunodeficiency virus 1 antibody indeterminate^SCT]
Indeterminate [82334004^Indeterminate^SCT]	**Indeterminate** [82334004^Indeterminate^SCT]	**HIV Indeterminate** [82334004^Indeterminate^SCT]

Preferred method of reporting Bio-Rad Geenius HIV 1/2 Supplemental System (example):

OBR|1||26848864580|80203-3^HIV 1 and 2 Ab^LN^083955^Panel 083955^L…

OBX|1|CE|68961-2^HIV 1 Ab^LN^083941^HIV 1 Ab^L||10828004^Positive^SCT…

OBX|2|CE|81641-3^HIV 2 Ab^LN^083942^HIV 2 Ab^L||260385009^Negative^SCT…

OBX|3|CE|80203-3^HIV 1 and 2 Ab^LN^083954^Interpretation:^L||89293008^Human immunodeficiency virus type 1^SCT…

Roche cobas HIV-1/HIV-2 Qualitative Nucleic Acid Text (example)

Report as two OBX segments

OBX|1|CE|25835-0^HIV 1 RNA^LN^139826^HIV-1 RNA^L|1|11214006^Reactive^SCT…
OBX|2|CE|69353-1^HIV 2 RNA^LN^139827^HIV-2 RNA^L|2|131194007^Non-Reactive^SCT…

HIV-1 Quantitative Viral Load tests and how to report

The Abbott RealTime HIV-1 Assay Quantitative and Roche COBAS® HIV-1 Test Quantitative tests are commonly performed HIV Viral Load tests.

- Laboratories should report a numeric copy value (e.g., XX,XXX copies/mL) as one OBX segment.
- Laboratories should NOT report log values.
- Laboratories should report a <20 value and a corresponding interpretation (i.e., Detected, Not Detected) as two OBX segments, if possible.

The possible combinations and preferred methods for reporting are listed below. Laboratories may have cutoff values of <20, <30, or <40. However, only <20 is shown below.

Numeric copy value (XX,XXX copies/mL) (example):

OBX|1|SN|20447-9^HIV 1 RNA^LN^HIVCOP^HIV Quant^L^2.72^v1^HIV Quant|1|^154|cpy/mL^^UCUM^cpy/mL^^L^1.1^v1…

<20 Detected (example):

Option 1:

OBX|1|SN|20447-9^HIV 1 RNA^LN^HIVCOP^HIV Quant^L^2.72^v1^HIV Quant|1|<^20|cpy/mL^^UCUM^cpy/mL^^L^1.1^v1…
OBX|2|CWE|20447-9^HIV 1 RNA^LN^HIVQNR^HIV-1, Quant,RNA^L^2.72^v1^HIV-1, Quant,RNA|1|260373001^Detected^SCT^DET^DETECTED^L^^v1…

Option 2:

OBX|1|ST|20447-9^HIV 1 RNA^LN^HIVCOP^HIV Quant^L^2.72^v1^HIV Quant|1|<20 DETECTED|cpy/mL^^UCUM^cpy/mL^^L^1.1^v1…

<20 Not Detected (example):

Option 1:

OBX|1|SN|20447-9^HIV 1 RNA^LN^HIVCOP^HIV Quant^L^2.72^v1^HIV Quant|1|<^20|cpy/mL^^UCUM^cpy/mL^^L^1.1^v1…
OBX|2|CWE|20447-9^HIV 1 RNA^LN^HIVQNR^HIV-1, Quant,RNA^L^2.72^v1^HIV-1, Quant,RNA|1|260415000^Not Detected^SCT…

Option 2:

OBX|1|ST|20447-9^HIV 1 RNA^LN^HIVCOP^HIV Quant^L^2.72^v1^HIV Quant|1|<20 NOT DETECTED|cpy/mL^^UCUM^cpy/mL^^L^1.1^v1…

CD4+T-Lymphocyte count and percent tests and how to report

All values of CD4+T-Lymphocyte count and percentage tests are reportable. Laboratories should attempt to filter and report only CD4 counts and percentages for patients known to be HIV-positive.

Preferred method of reporting CD4 counts and percentages (example):

OBX|1|NM|24467-3^CD3+CD4+ Cells # XXX^LN^1230001983^CD4/CD3 DUAL (T HELPER)^LABRSLTOUT^2.44||164|ABS/mm3…

OBX|2|NM|8123-2^CD3+CD4+ Cells NFr XXX^LN^1230001984^CD4/CD3 DUAL (T HELPER)%^LABRSLTOUT^2.44||22.4|%...

Contact information

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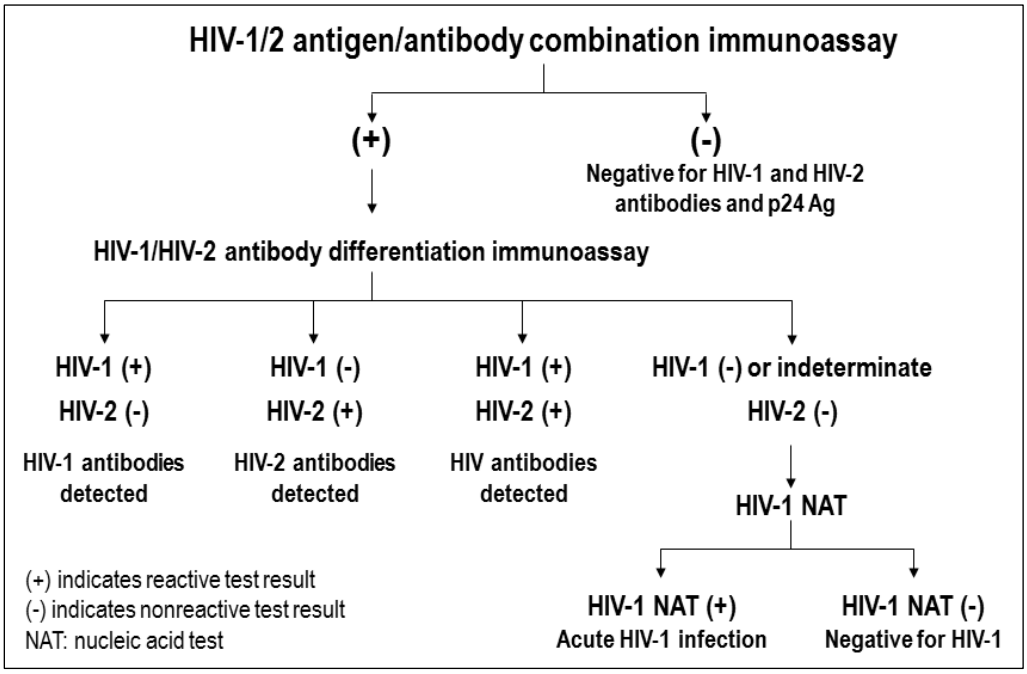
Website: https://odh.ohio.gov/wps/portal/gov/odh/know-our-programs/hiv-aids-surveillance-program/Reporting

Test Category	Manufacturer/Test Name	Analyte/OBX	Preferred LOINC	Results SNOMED	Specimen Type
Screening Ag/Ab Alere Determine (point-of-care rapid)	Alere Determine HIV-1/2 Ag/Ab Combo Test	HIV 1 Ab + HIV 2 Ab & HIV 1 p24 Ag	75666-8	Ab positive [259855002^Human immunodeficiency virus antibody^SCT] Ag (p24) positive [713008009^Human immunodeficiency virus p24 antigen positive^SCT] Negative [260385009^Negative^SCT] Invalid [455371000124106^Invalid result^SCT]	119364003^Serum specimen^SCT 119361006^Plasma specimen^SCT 122554006^Capillary blood specimen^SCT 122555007^Venous blood specimen^SCT
Screening Ag/Ab	Abbott HIV Ag/Ab Combo Assay	HIV 1 Ab + HIV 2 Ab + HIV 1 p24 Ag	56888-1	Reactive [11214006^Reactive^SCT] Nonreactive [131194007^Non-Reactive^SCT]	119364003^Serum specimen^SCT 119361006^Plasma specimen^SCT
Screening Ag/Ab	Bio-Rad GS HIV Combo Ag/Ab EIA	HIV 1 Ab + HIV 2 Ab + HIV 1 p24 Ag	56888-1	Reactive [11214006^Reactive^SCT] Nonreactive [131194007^Non-Reactive^SCT]	119364003^Serum specimen^SCT 119361006^Plasma specimen^SCT
Screening Ag/Ab Bioplex	Bio-Rad HIV Ag/Ab Assay (5th gen)	HIV 1 Ab & HIV 2 Ab & HIV 1 p24 Ag	85037-0 (Order Code)	N/A	
		HIV 1 Ab & HIV 2 Ab & HIV 1 p24 Ag	56888-1	Reactive [11214006^Reactive^SCT] Nonreactive [131194007^Non-Reactive^SCT]	
		HIV 1 Ab	29893-5	Reactive [11214006^Reactive^SCT] Reactive, undifferentiated - [472451000124100^Reactive, undifferentiated ^SCT] Nonreactive [131194007^Non-Reactive^SCT]	
		HIV 1 p24 Ag	18396-2	Reactive [11214006^Reactive^SCT] Nonreactive [131194007^Non-Reactive^SCT] Not reportable due to high HIV Ab level - [471841000012410^Not reportabe due to high HIV Ab level^SCT]	
		HIV 2 Ab	30361-0	Reactive [11214006^Reactive^SCT] Reactive, undifferentiated - [472451000124100^Reactive, undifferentiated ^SCT] Nonreactive [131194007^Non-Reactive^SCT]	119364003^Serum specimen^SCT 119361006^Plasma specimen^SCT
Confirmatory	Bio-Rad Geenius HIV 1/2 Supplemental System (4th gen)	HIV 1 Ab & HIV 2 Ab	89365-1 (Order Code)	N/A	
		HIV 1 Ab & HIV 2 Ab	80203-3	HIV 1 Positive [89293008^Human immunodeficiency virus type 1^SCT] HIV 2 positive [36115006^Human immunodeficiency virus type 2^SCT] HIV 1 indeterminate [719727000^Human immunodeficiency virus 1 antibody indeterminate^SCT] HIV 2 indeterminate [719767004^Human immunodeficiency virus 2 antibody indeterminate^SCT] HIV indeterminate [82334004^Indeterminate^SCT] HIV negative [260385009^Negative^SCT] HIV-2 positive with HIV-1 cross reactivity [719789000^Human immunodeficiency virus 2 antibody positive and Human immunodeficiency virus 1 antibody cross-reactivity^SCT] HIV positive untypable [713742005^Human immunodeficiency virus antibody positive^SCT]	
		HIV 1 Ab	68961-2	HIV 1 Negative [260385009^Negative^SCT] Indeterminate [82334004^Indeterminate^SCT] Positive [10828004^Positive^SCT]	119364003^Serum specimen^SCT
		HIV 2 Ab	81641-3	HIV 2 Negative [260385009^Negative^SCT] Indeterminate [82334004^Indeterminate^SCT] Positive [10828004^Positive^SCT]	119361006^Plasma specimen^SCT 122554006^Capillary blood specimen^SCT 122555007^Venous blood specimen^SCT
HIV-1/HIV-2 qualitative nucleic acid tests (NAT)	Roche cobas HIV-1/HIV-2 Qualitative Nucleic Acid Test	HIV 1 RNA/HIV 2 RNA (Qualitative)	96557-4 (Order Code)	Reactive [11214006^Reactive^SCT] Nonreactive [131194007^Non-Reactive^SCT] Invalid [455371000124106^Invalid result^SCT]	119364003^Serum specimen^SCT 119361006^Plasma specimen^SCT
		HIV 1 RNA/HIV 2 RNA (Qualitative)	85368-9		
		HIV 1 RNA (Qualitative)	25835-0		
		HIV 2 RNA (Qualitative)	69353-1		
HIV-1 quantitative Viral Load	Abbott RealTime HIV-1 Assay Quantitative	HIV 1 RNA (Quantitative)	20447-9	Not detected [260415000^Not detected^SCT] Below threshold level [260988000^Below threshold level^SCT] Above threshold level [260981006^Above threshold level^SCT] copies/mL	119361006^Plasma specimen^SCT
HIV-1 quantitative Viral Load	Roche COBAS® HIV-1 Test Quantitative	HIV 1 RNA (Quantitative)	20447-9	Not detected [260415000^Not detected^SCT] Below threshold level [260988000^Below threshold level^SCT] Above threshold level [260981006^Above threshold level^SCT] copies/mL	119361006^Plasma specimen^SCT
CD4 Count	CD4 T cell count	N/A	24467-3	uL	122555007^Venous blood specimen^SCT
CD4 Percent	CD4 T cell percent	N/A	8123-2	%	122555007^Venous blood specimen^SCT

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 test for established HIV-1 or HIV-2 infection 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.*

Reporting results from the HIV diagnostic testing algorithm to persons ordering HIV tests and public health authorities

Test performed	Test results	Final interpretation for provider report	Test results to be reported to public health authorities
1. HIV-1/2 Ag/Ab combination immunoassay	1. Nonreactive	Negative for HIV-1 antigen and HIV-1/HIV-2 antibodies. No laboratory evidence of HIV infection. If acute HIV infection is suspected, consider testing for HIV-1 RNA.	Reporting this test result is not required.
1. HIV-1/2 Ag/Ab combination immunoassay 2. HIV-1/HIV-2 antibody differentiation immunoassay	1. Reactive 2. HIV-1 reactive and HIV-2 nonreactive	Positive for HIV-1 antibodies. Laboratory evidence consistent with established HIV-1 infection is present.	Report test results 1 and 2.
1. HIV-1/2 Ag/Ab combo immunoassay 2. HIV-1/HIV-2 antibody differentiation immunoassay	1. Reactive 2. HIV-1 nonreactive and HIV-2 reactive	Positive for HIV-2 antibodies. Laboratory evidence of HIV-2 infection is present.	Report test results 1 and 2.
1. HIV-1/2 Ag/Ab combination immunoassay 2. HIV-1/HIV-2 antibody differentiation immunoassay 3. HIV-1 RNA assay	1. Reactive 2. Nonreactive or indeterminate 3. RNA not detected	HIV antibodies were not confirmed and HIV-1 RNA was not detected. No laboratory evidence of HIV-1 infection. Follow-up testing for HIV-2 should be performed if clinically indicated.	Reporting this test result is not required.
1. HIV-1/2 Ag/Ab combination immunoassay 2. HIV-1/HIV-2 antibody differentiation immunoassay 3. HIV-1 RNA assay	1. Reactive 2. Nonreactive 3. RNA detected	Positive for HIV-1. Laboratory evidence consistent with acute HIV-1 infection is present.	Report test results 1, 2, and 3.
1. HIV-1/2 Ag/Ab combination immunoassay 2. HIV-1/HIV-2 antibody differentiation immunoassay 3. HIV-1 RNA assay	1. Reactive 2. Indeterminate 3. RNA detected	Positive for HIV-1 antibodies. Laboratory evidence of HIV-1 infection confirmed by HIV-1 RNA.	Report test results 1, 2, and 3.
1. HIV-1/2 Ag/Ab combination immunoassay 2. HIV-1/HIV-2 antibody differentiation immunoassay	1. Reactive 2. HIV-1 and HIV-2 reactive	Positive for HIV antibodies. Laboratory evidence of HIV infection is present. HIV antibodies could not be differentiated as HIV-1 or HIV-2. Additional testing for HIV-1 RNA or HIV-2 RNA should be performed if clinically indicated.	Report test results 1 and 2.
1. HIV-1/2 Ag/Ab combination immunoassay 2. HIV-1/HIV-2 antibody differentiation immunoassay	1. Reactive 2. Nonreactive or indeterminate	HIV-1 antibodies were not confirmed and HIV-1 RNA testing was not performed. Testing of this specimen is incomplete. Follow-up testing for HIV antibodies and HIV-1 RNA is recommended as soon as possible.	Report test results 1 and 2.

Abbreviations: Ag/Ab, antigen/antibody; RNA, ribonucleic acid.

Adapted from *Interim Guidelines for Laboratories on the Use of a New Diagnostic Testing Algorithm for Human Immunodeficiency Virus (HIV) Infection.* New York State Department of Health (http://www.health.ny.gov/diseases/aids/providers/regulations/testing/docs/guidelines_diagnostic_testing.pdf).