NEW YORK STATE OF OPPORTUNITY. Department of Health

KATHY HOCHUL
Governor

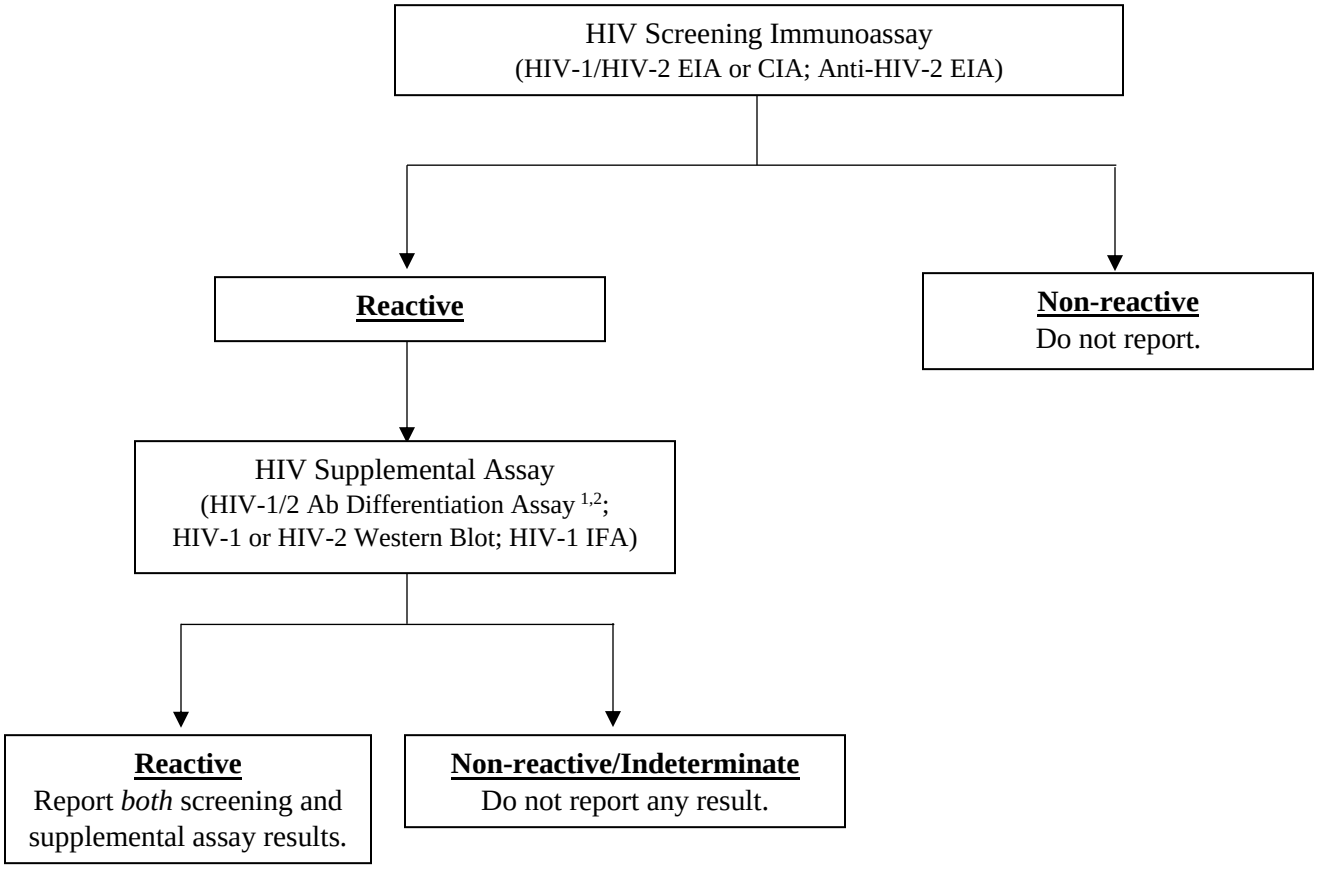
JAMES V. McDONALD, M.D., M.P.H.
Commissioner

JOHANNE E. MORNE, M.S.
Executive Deputy Commissioner

Guidance for Reporting Results of HIV-related Donor Testing to the New York State Department of Health

New York State Public Health Law and Regulations require that all blood banks and tissue banks report all determinations of HIV infection, HIV-related illness, and AIDS to the New York State Department of Health. Reports are required for New York State residents and for collection sites located within New York State regardless of the donor's residence. The following algorithms summarize the required reportable HIV results by testing algorithm.

Algorithm A: Reactive/repeatedly reactive HIV Screening Immunoassay and Supplemental Assay[1]

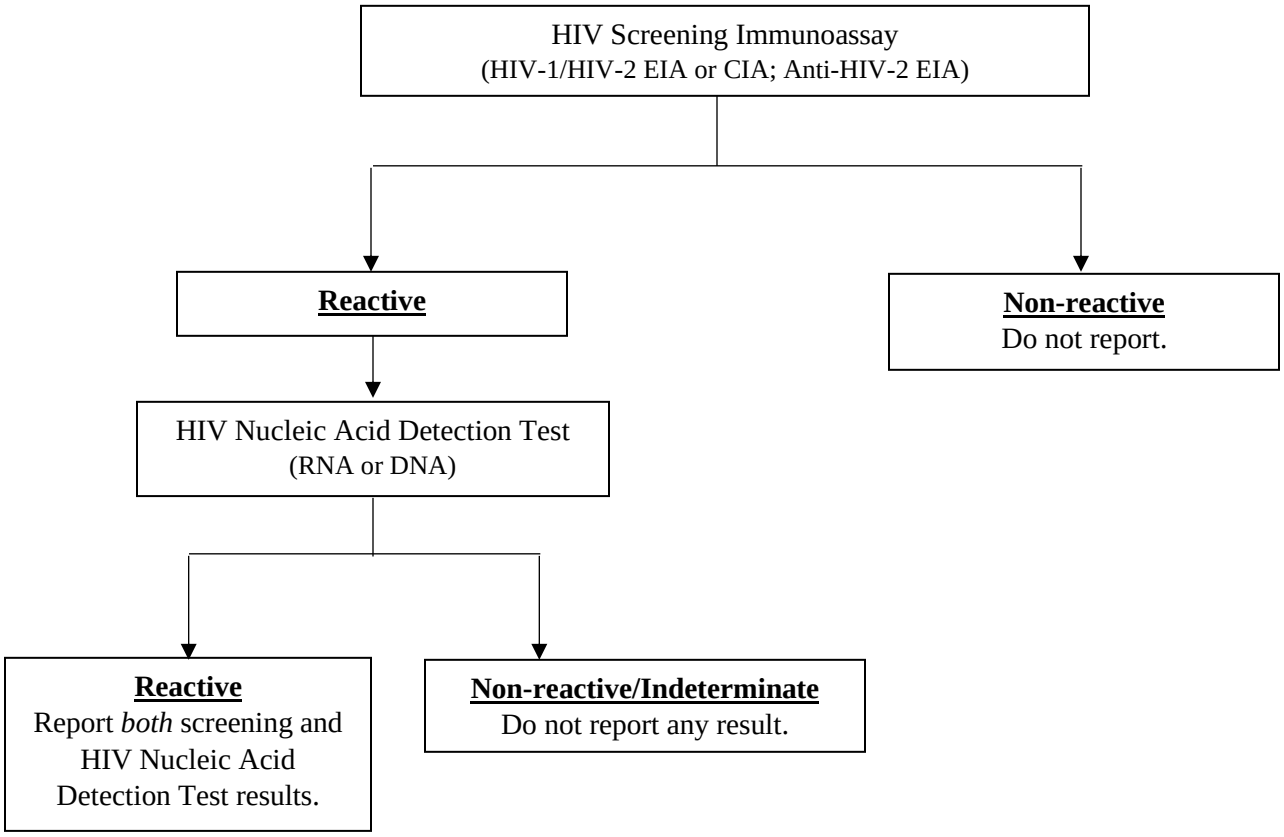


Please report the result according to the manufacturer's package insert. Please refer to the New York State Department of Health Laboratory Reporting and Specimen Submission Requirements for Communicable Diseases or contact the Bureau of HIV/AIDS Epidemiology at 518-474-4284 or bhaelab@health.ny.gov for more information on HIV-related donor testing reportable to the New York State Department of Health.

[1] U.S. Food and Drug Administration approved Geenius HIV-1/2 Supplemental Assay for the confirmation and differentiation of antibodies to HIV-1 and HIV-2 in serum or plasma samples from blood donors in August, 2019.
[2] Clients should be advised that this test may not identify acute HIV infection; additional testing using the Centers for Disease Control and Prevention HIV Diagnostic Testing Algorithm may be required.

Algorithm B: Reactive/repeatedly reactive HIV Screening Immunoassay and HIV Nucleic Acid Detection Test

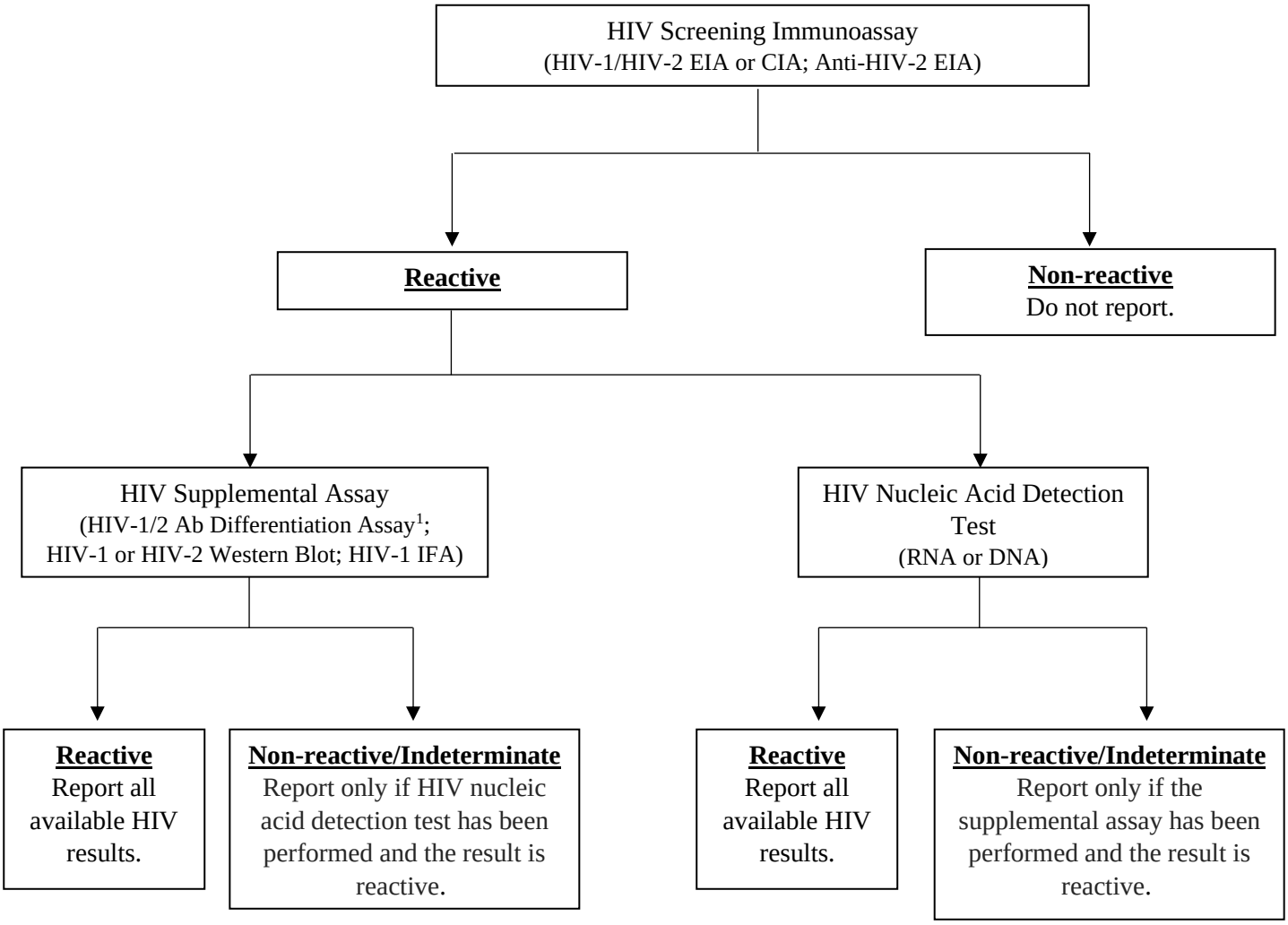
Results from pooled nucleic acid amplification test do not need to be reported; however, the result(s) of individual positive test(s) should be reported.



Please report the result according to the manufacturer's package insert. Please refer to the New York State Department of Health Laboratory Reporting and Specimen Submission Requirements for Communicable Diseases or contact the Bureau of HIV/AIDS Epidemiology at 518-474-4284 or bhaelab@health.ny.gov for more information on HIV-related donor testing reportable to the New York State Department of Health.

Algorithm C: Reactive/repeatedly reactive HIV Screening Immunoassay, Supplemental Assay and HIV Nucleic Acid Detection Test

Results from pooled nucleic acid amplification test do not need to be reported; however, the result(s) of individual positive test(s) should be reported.



Please report the result according to the manufacturer's package insert. Please refer to the New York State Department of Health Laboratory Reporting and Specimen Submission Requirements for Communicable Diseases or contact the Bureau of HIV/AIDS Epidemiology at 518-474-4284 or bhaelab@health.ny.gov for more information on HIV-related donor testing reportable to the New York State Department of Health.

[1] U.S. Food and Drug Administration approved Geenius HIV-1/2 Supplemental Assay for the confirmation and differentiation of antibodies to HIV-1 and HIV-2 in serum or plasma samples from blood donors in August, 2019.