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Diagnostic Immunology Standard of Practice 1 (DI S1): Syphilis Screening Algorithm Using Nontreponemal Tests All initial reactive nontreponemal tests must be confirmed using a standard treponemal test unless the patient has had a known documented prior syphilis infection or the report contains a statement, in addition to the requirements in Reporting Standard of Practice 2, that the test has not been confirmed.	An initial test refers to the first or only test in the laboratory's protocol for syphilis testing. This is the standard CDC recommended protocol where screening for syphilis is performed with a non-treponemal test such as RPR, followed by a treponemal test if the non-treponemal test is reactive. Additional information is available at: https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6005a1.htm. Laboratories may use prior information to verify that confirmatory testing has been performed.
Diagnostic Immunology Standard of Practice 2 (DI S2): Syphilis Screening Algorithm Using Treponemal Tests Syphilis screening algorithms using a treponemal enzyme or chemiluminescence immunoassay (EIA/CIA) initial tests must have a rapid plasma reagin (RPR) performed on all reactive sera. If the results are discordant, the laboratory must: a) perform a treponemal assay other than EIA/CIA; or b) indicate on the report that a confirmatory treponemal test is recommended in addition to the requirements in Reporting Standard of Practice 2.	This is called the Reverse Sequence Syphilis Screening protocol and is the alternative to the standard CDC protocol defined in Diagnostic Immunology Sustaining Standard of Practice 1. Laboratories may follow the standard protocol or the Reverse Sequence Syphilis Screening protocol. If results are discordant in the Reverse protocol, CDC recommends that an alternate treponemal test be performed using a method different from the initial treponemal test, such as *Treponema pallidum* particle agglutination (TP-PA). Reference: MMWR 2011 Vol. 60, No. 5.
Diagnostic Immunology Standard of Practice 3 (DI S3): Non-Treponemal End Point Titration Diagnostic specimens found reactive for syphilis reagin antibody must be titrated to the end point onsite or referred to	For specimens obtained from residents outside of New York City, results of titers greater than or equal to sixteen (16) must be telephoned immediately to the State Health Department. On-site quantitation is considered to be met if:

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another laboratory holding a valid New York State clinical laboratory permit in the category of diagnostic immunology.	• the facility has an indication to initiate on-site treatment; and • the same sample is forwarded for quantitation and confirmation to a New York State permitted laboratory holding a valid permit in the category of diagnostic immunology. Non-diagnostic specimens, such as insurance or donor testing, where the results are not reported to the health care provider, do not need to be titrated.
Diagnostic Immunology Standard of Practice 4 (DI S4): Food Allergy Testing The laboratory must use immunoglobin E (IgE) based assays for food allergy testing unless the laboratory receives approval from the Department for a laboratory developed test (LDT).	Validation studies for other immunologic tests must be submitted for review and must be approved prior to offering testing. Please refer to the CLEP Submission Guidelines and the Guidelines for the Diagnosis and Management of Food Allergy in the United States when submitting a validation package. Validation Guidelines are posted on the CLEP website at: https://www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/test-approval.
Diagnostic Immunology Standard of Practice 5 (DI S5): Reporting Preliminary Positive HIV Test Results According to New York State regulations (Section 58-8.4), laboratories may report preliminary positive HIV test results to a physician or other persons authorized by law to request an HIV test, provided that: a) the laboratory has written policies and procedures for provision of preliminary positive HIV test results; and b) in addition to the requirements in Reporting Standard of Practice 2, the report clearly states:	A preliminary positive HIV result is one that has not been substantiated with HIV supplemental test(s).

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i. that the finding is preliminary; ii. that results of confirmatory testing will follow; and iii. that such confirmatory results must be considered in making a diagnosis related to HIV infection.	
Diagnostic Immunology Standard of Practice 6 (DI S6): Timeliness of Reporting Results for Expedited Maternal/Newborn HIV Testing Laboratories conducting expedited maternal/newborn HIV testing as mandated by Section 69-1.3 must: a) establish and implement procedures to ensure identification of such specimens; b) report initial HIV test results (negative or preliminary positive) within twelve (12) hours of obtaining consent for maternal testing or within twelve (12) hours of birth when expedited newborn testing is performed in lieu of maternal testing; and c) either perform supplemental testing intended to confirm a preliminary positive test result and report results within four (4) days of obtaining the preliminary positive result or refer a specimen for such testing within twenty-four (24) hours of obtaining the preliminary positive result.	b) Up to twelve (12) hours is the allowable timeframe for reporting initial test results. However, results from the initial test should be transmitted as soon as possible, preferably within one (1) hour of specimen collection. This is intended to facilitate the initiation of antiretroviral prophylaxis to reduce the risk of perinatal transmission. c) Up to four (4) days is the allowable timeframe for reporting results of supplemental testing performed to confirm a preliminary positive result; however, supplemental test results should be transmitted as soon as possible.

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Diagnostic Immunology Standard of Practice 7 (DI S7): Reporting Results from Anonymous HIV Testing on Specimens from Occupational Exposure Source Patients According to Part 63 of the NYCRR Title 10, laboratories that perform HIV testing on specimens from occupational exposure source patients from whom consent for HIV testing cannot be obtained must: a) have a policy and/or procedure in place to allow for anonymous testing; and b) report the results of HIV tests only to the authorized submitter using only the specimen code and no patient-identifying information.	Part 63 of Title 10 of the NYCRR indicates that informed consent for HIV testing is not required for anonymous testing of a person who is the source of an occupational exposure, who is deceased, comatose, or otherwise unable to provide consent, and for whom no person authorized to consent on behalf of the source patient is immediately available. a) Submitters should be instructed to use a unique code that will identify the specimen but maintain the anonymity of the source patient involved in an occupational exposure when consent for HIV testing could not be obtained from the source patient. b) Only the attending health care professional (submitter) of the *exposed* person is authorized to submit specimens and receive results for anonymous HIV testing of an occupational exposure source patient from whom consent could not be obtained.