

Diagnostic Immunology	
Former Standard and Guidance	Proposed Standard and Guidance
<p>The following specialty sustaining standards of practices shall be incorporated into the laboratory's quality management system, where applicable to the scope of services provided. Laboratories performing donor testing must comply with Subpart 58-2.</p> <p>DI S1 through DI S3 effective May 11, 2012; DI S4 effective September 27, 2012; DI S5 through DI S7 effective July 25, 2012.</p>	<p>Deleted</p>
<p>Diagnostic Immunology Sustaining Standard of Practice 1 (DI S1): Syphilis Screening Algorithm Using Nontreponemal Tests</p> <p>All initial reactive nontreponemal tests shall be confirmed using a standard treponemal test unless the patient has had a known documented prior syphilis infection or the report contains a statement that the test has not been confirmed.</p> <p>Guidance – An initial test refers to the first or only test in the laboratory's protocol for syphilis testing.</p> <p>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.</p> <p>Laboratories may use prior information to verify that confirmatory testing has been performed.</p>	<p>Diagnostic Immunology Standard of Practice 1 (DI S1): Syphilis Screening Algorithm Using Nontreponemal Tests</p> <p>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.</p> <p>Guidance –</p> <p>An initial test refers to the first or only test in the laboratory's protocol for syphilis testing.</p> <p>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.</p> <p>Additional information is available at: https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6005a1.htm.</p> <p>Laboratories may use prior information to verify that confirmatory testing has been performed.</p>

Diagnostic Immunology	
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<p>Diagnostic Immunology Sustaining Standard of Practice 2 (DI S2): Syphilis Screening Algorithm Using Treponemal Tests</p> <p>Syphilis screening algorithms using a treponemal enzyme or chemiluminescence immunoassay (EIA/CIA) initial test shall have an RPR performed on all reactive sera. If the results are discordant, the laboratory must either perform a treponemal assay other than EIA/CIA or indicate on the report that a confirmatory treponemal test is recommended.</p> <p>Guidance – 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 methodology different from the initial treponemal test, such as <i>Treponema pallidum</i> particle agglutination (TP-PA). Reference: MMWR 2011 Vol. 60, No. 5.</p>	<p>Diagnostic Immunology Standard of Practice 2 (DI S2): Syphilis Screening Algorithm Using Treponemal Tests</p> <p>Syphilis screening algorithms using a treponemal enzyme or chemiluminescence immunoassay (EIA/CIA) initial tests must have a rapid plasma regain (RPR) performed on all reactive sera. If the results are discordant, the laboratory must:</p> <ul style="list-style-type: none"> 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. <p>Guidance –</p> <p>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 <i>Treponema pallidum</i> particle agglutination (TP-PA). Reference: MMWR 2011 Vol. 60, No. 5.</p>
<p>Diagnostic Immunology Sustaining Standard of Practice 3 (DI S3): Non-Treponemal End Point Titration</p> <p>Diagnostic specimens found reactive for syphilis-reagin antibody shall be titrated to the end point onsite</p> <p>Guidance – Arbitrary limits to titrating patient specimens (e.g.</p>	<p>Diagnostic Immunology Standard of Practice 3 (DI S3): Non-Treponemal End Point Titration</p> <p>Diagnostic specimens found reactive for syphilis reagin antibody must be titrated to the end point onsite or referred to another laboratory holding a valid New York State clinical</p>

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<p>greater than 512) are not acceptable.</p> <p>For specimens obtained from residents outside of New York City, results of titers greater than or equal to 16 must be telephoned immediately to the State Health Department.</p> <p>The requirement for on-site quantitation is considered to be met if:</p> <ol style="list-style-type: none"> a) the facility has an indication to initiate on-site treatment; b) the same sample is forwarded for quantitation and confirmation to an approved laboratory; c) the laboratory documents ongoing comparison of the on-site RPR test result for each patient with the result obtained by the referral laboratory; and, d) as part of its quality assurance program, the laboratory investigates discordant results and initiates timely and appropriate corrective action, if necessary. The data should be retained and be available for Department review. <p>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.</p>	<p>laboratory permit in the category of diagnostic immunology.</p> <p>Guidance –</p> <p>For reporting requirements, refer to the Laboratory Reporting of Communicable Diseases guidelines, available at: https://wadsworth.org/regulatory/clep/laws.</p> <p>On-site quantitation is considered to be met if:</p> <ul style="list-style-type: none"> 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. <p>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.</p>
<p>Diagnostic Immunology Sustaining Standard of Practice 4 (DI S4): Food Allergy Testing</p> <p>The laboratory shall use IgE based assays for food allergy testing unless written approval to use other immunologic tests have been received from the Department.</p> <p>Guidance – 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</p>	<p>Diagnostic Immunology Standard of Practice 4 (DI S4): Food Allergy Testing</p> <p>The laboratory must use immunoglobulin E (IgE) based assays for food allergy testing unless the laboratory receives approval from the Department for a laboratory developed test (LDT).</p> <p>Guidance –</p> <p>Validation studies for other immunologic tests must be</p>

Diagnostic Immunology	
Former Standard and Guidance	Proposed Standard and Guidance
<p>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 http://www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/test-approval.</p>	<p>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.</p>
<p>Standard 5 (DI S5): Reporting Preliminary Positive HIV Test Results</p> <p>In accordance with NYSDOH regulations (Section 58-8.4) laboratories may report preliminary positive HIV test results to a physician or other person legally authorized to request an HIV test, provided that:</p> <ul style="list-style-type: none"> a) the laboratory has written policies and procedures for provision of preliminary positive HIV test results; b) the report prominently and clearly states that the finding is preliminary, that results of confirmatory testing will follow, and that such confirmatory results must be considered in making a diagnosis related to HIV infection. <p>Guidance – A preliminary positive HIV result is one that has not been substantiated with HIV supplemental test(s).</p>	<p>Standard 5 (DI S5): Reporting Preliminary Positive HIV Test Results</p> <p>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:</p> <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> 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. <p>Guidance –</p> <p>A preliminary positive HIV result is one that has not been substantiated with HIV supplemental test(s).</p>

Diagnostic Immunology	
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<p>Diagnostic Immunology Sustaining Standard of Practice Standard 6 (DI S6): Timeliness of Reporting Results for Expedited Maternal/Newborn HIV Testing</p> <p>Laboratories conducting expedited maternal/newborn HIV testing as mandated by Section 69-1.3 shall:</p> <ul style="list-style-type: none"> a) establish and implement procedures to ensure identification of such specimens; b) report initial HIV test results (negative or preliminary positive) within 12 hours of obtaining consent for maternal testing or within 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 4 days of obtaining the preliminary positive result or refer a specimen for such testing within 24 hours of obtaining the preliminary positive result. <p>Guidance – a) This standard is intended to facilitate the birthing facility's compliance with the regulatory requirements for obtaining HIV results of expedited maternal/newborn HIV testing. The laboratory's SOPM should describe procedures and protocols specific to specimen handling, including the need for the birthing facility to record either the time of the mother providing consent for testing or the time of the infant's birth; the specimen collection time; reporting of preliminary results; and where necessary, arrangements for prompt referral for screen and/or supplemental testing. Refer to Specimen Processing Sustaining Standard of Practice 5 (Processing S5): Urgent Test Request.</p>	<p>Diagnostic Immunology Sustaining Standard of Practice Standard 6 (DI S6): Timeliness of Reporting Results for Expedited Maternal/Newborn HIV Testing</p> <p>Laboratories conducting expedited maternal/newborn HIV testing as mandated by Section 69-1.3 must:</p> <ul style="list-style-type: none"> 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. <p>Guidance –</p> <ul style="list-style-type: none"> 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. b) 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

Diagnostic Immunology	
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<p>b) Up to 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 1 hour of specimen collection. This is intended to facilitate the initiation of antiretroviral prophylaxis to reduce the risk of perinatal transmission.</p> <p>b) Up to 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.</p>	<p>results should be transmitted as soon as possible.</p>
<p>Diagnostic Immunology Sustaining Standard of Practice Standard 7 (DI S7): Reporting Results From Anonymous HIV Testing on Specimens From Occupational Exposure Source Patients</p> <p>In accordance with 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 can not be obtained shall:</p> <ul style="list-style-type: none"> a) have a policy and/or procedure in place to allow for anonymous testing in such circumstances; and b) report the results of HIV tests only to the authorized submitter using only the specimen code and no patient-identifying information. <p>Guidance – 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</p>	<p>Diagnostic Immunology Standard of Practice Standard 7 (DI S7): Reporting Results from Anonymous HIV Testing on Specimens from Occupational Exposure Source Patients</p> <p>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 can not be obtained must:</p> <ul style="list-style-type: none"> 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. <p>Guidance –</p> <p>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</p>

Diagnostic Immunology	
Former Standard and Guidance	Proposed Standard and Guidance
<p>available.</p> <p>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.</p> <p>Only the attending health care professional (submitter) of the <i>exposed</i> 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.</p>	<p>consent, and for whom no person authorized to consent on behalf of the source patient is immediately available.</p> <p>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.</p> <p>Only the attending health care professional (submitter) of the <i>exposed</i> 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.</p>