

Diagnostic Immunology		
Tag #	Standard	Guidance
	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.	
D11	<p>Diagnostic Immunology Standard 1</p> <p>Criteria for degrees of agglutination and lysis shall be defined for quantitative serologic procedures.</p>	
D12	<p>Diagnostic Immunology Standard 2</p> <p>Red cell suspensions used for quantitative serologic procedures shall be standardized to indicate cell concentration (photometrically or with some other alternate procedure).</p>	
D13	<p>Diagnostic Immunology Standard 3</p> <p>All reactive nontreponemal tests should 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>	Laboratories may use prior information to verify that confirmatory testing has been performed or the need for confirmatory testing can be indicated on the requisition.

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DI4	<p>Diagnostic Immunology Standard 4</p> <p>Diagnostic specimens found reactive for syphilis-reagin antibody shall be titered to the end point on site.</p>	<p>Arbitrary cut-off reports (e.g., greater than 1:512) are not acceptable.</p> <p>Results of all confirmed positive syphilis tests should be reported to the State Health Department as mandated under Section 2102 of the Public Health Law.</p> <p>The requirement for on-site quantitation is considered to be met if:</p> <ul 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.

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DI5	<p>Diagnostic Immunology Standard 5</p> <p>If the results of non-diagnostic specimens found to be reactive for syphilis-reagin antibody are reported to the donor/client, samples shall be titered to the end point.</p>	<p>Donor and insurance specimens are considered to be nondiagnostic.</p> <p>If results of nondiagnostic specimens found to be reactive for syphilis-reagin antibody are not reported, specimens need not be titered.</p> <p>If titering is performed on nondiagnostic specimens, it does not need to be done on-site.</p> <p>If results of confirmed positive syphilis tests are reported to the donor/client, they should also be reported to the New York State Health Department as mandated under Section 2102 of the Public Health Law.</p>

Human Immunodeficiency Virus (HIV)		
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	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.	
	GENERAL STANDARDS	
HIV1	HIV Standard 1	The standard has been deleted. The laboratory is not required to notify the Department of changes in HIV kit manufacturer, HIV test procedure, and addition of any new HIV test procedure.
	HIV Standard 2	Standard has been deleted. Number reserved.
HIV3	HIV Standard 3 The laboratory shall establish a protocol for distinguishing diagnostic and prognostic test requests.	This standard is applicable to nucleic acid tests for HIV that are FDA-cleared for prognosis or the monitoring of therapy/treatment of HIV infected persons. Any other use (e.g. patient diagnosis) is outside the license of the test. HIV RNA testing on antibody negative persons should not be performed without cautions/advisories to the physician concerning the false positive rate associated with these assays.

Human Immunodeficiency Virus (HIV)

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	<p>HIV Standard 4</p> <p>Laboratory reports for HIV tests shall:</p>	<p>ELISA results are not reportable as indeterminate. Results of qualitative DNA PCR are reportable as HIV DNA detected or not detected. Prognostic viral load determinations are reportable as the number of viral RNA copies per milliliter of plasma.</p>
HIV4a	a) indicate the test method;	
HIV4b	b) use standardized terminology for results that is generally accepted by experts in laboratory medicine;	Both diagnostic and technical limits of the method should be reported. General testing limitations, such as: "this report shall be interpreted in conjunction with clinical findings" are not required.
HIV4c	c) follow manufacturer's recommendations for reporting, including the limits of sensitivity, where applicable;	
HIV4d	d) indicate the complete result of each test and shall be formatted so that results from the complete testing algorithm are viewable together; and,	The diagnostic limitation that PCR may not detect HIV infection in infants in the first months of life should be included, where applicable, and should indicate a recommendation for re-testing.
HIV4e	e) include a recommendation for follow-up testing if confirmatory test results do not agree with antibody screen results.	d) For <u>diagnostic</u> testing, acceptable formatting would be the display, on a single page, of results for all tests performed on each specimen. For other than diagnostic testing, more than one individual's test results may be listed on a page.
		It is recommended that reports which transmit diagnostic Western blot positive results include a statement regarding a providers authority under Article 27F to provide spousal notification.
	<p>HIV Standard 5</p> <p>A laboratory operating under contract to a blood bank shall provide, upon request, information on individual test reactions for HIV tests performed for donor purposes.</p>	
HIV5		The information should include values for each of the replicate tests relative to the laboratory's established cut-off (e.g., OD, fluorescence reading).

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HIV6	<p>HIV Standard 6</p> <p>A weakly reactive control, within the low to mid positive linear range of the assay, shall be run:</p> <p>a) in every plate for ELISA microplate procedures;</p> <p>b) in every tray for bead format procedures; and,</p> <p>c) with every batch of ten or less specimens for confirmatory assays (e.g., Western blots or IFA).</p>	<p>Also refer to Section 58-8.2.</p> <p>NOTE: A weakly reactive control may be a kit control, an external control, a purchased control material independent of the kit type being validated, stored specimens of verified reactivity, or other similar non-kit control or calibration material that meets one of the following definition:</p> <p>a) for the ELISA antibody screen, an O.D. to cutoff ratio of at least 1, but no greater than the mid-point of the reportable range;</p> <p>b) for the Western blot, ELISA reactive and minimally a p24 band present; and,</p> <p>c) for qualitative DNA PCR, a HIV target number 2 - 3 times the established limit of the detection of the assay.</p> <p>A negative (non-reactive) control may be used in lieu of the weakly reactive control for Western blot and IFA tests performed for diagnostic purposes when the laboratory test population has a confirmatory rate of GREATER than 50%.</p> <p>A weakly reactive control is strongly recommended, but not required for:</p> <p>a) HIV viral load testing performed for prognostic purposes;</p> <p>b) HIV testing performed on individuals in conjunction with an application for insurance; and</p> <p>c) HIV testing of specimens obtained using an FDA approved consumer self-collection device.</p> <p>Donor testing must follow Part 59-2.3(b) and include a weakly reactive control with each run.</p>
ANTIBODY SCREENING: ELISA		

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HIV7a HIV7b	<p>HIV Standard 7</p> <p>For samples found to be reactive using the HIV1/HIV2 combination kits, an HIV1 Western Blot shall be performed; and,</p> <p>a) HIV1 reactive Western Blot report shall be reported as reactive for HIV1; or,</p> <p>b) HIV1 Western Blot nonreactive or indeterminate samples shall require additional testing by an HIV2 ELISA;</p> <p style="padding-left: 40px;">i) HIV2 ELISA nonreactive results shall be reported as nonreactive; and,</p> <p style="padding-left: 40px;">ii) HIV2 reactive results shall require additional testing using an HIV2 Western Blot.</p>	
HIV8	<p>CONFIRMATORY TESTING: WESTERN BLOT and IFA</p>	<p>If discrepant results are found, the laboratory shall attempt to resolve the discrepancy. This does not apply to donor testing if the results are not communicated to the subject of the test.</p>
	<p>HIV Standard 8</p> <p>When performing confirmatory testing on a specimen referred by another laboratory, a laboratory shall perform an antibody screen on specimens that give non-reactive or indeterminate results on the confirmatory test.</p>	
	<p>HIV Standard 9</p>	<p>Standard deleted. Number reserved for future use.</p>
HIV10	<p>HIV Standard 10</p> <p>If the result of P₂₄ antigen is to be communicated to the subject of the test, a positive antigen test performed for donor screening purposes shall be confirmed by retesting the specimen following neutralization.</p>	<p>This applies to HIV antigen testing for <u>blood</u> donor screening.</p>

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Molecular standards for HIV11-15 have been moved. Numbers are reserved for future use.		
HIV 16	EXPEDITED MATERNAL NEWBORN HIV TESTING	<p>The SOPM should document procedures specific to specimen handling, including recording the time of specimen collection; reporting of preliminary results; and where necessary, arrangements for prompt referral for screen and/or confirmatory testing. Results should be transmitted as soon as practicable directly to clinicians authorized to receive the test results. Reporting by phone, fax, or other electronic media is permissible as long as appropriate confidentiality procedures are followed and verbal results are immediately followed by a hard copy or electronic report.</p>
	<p>HIV Standard 16</p> <p>Laboratories performing expedited maternal/newborn HIV testing mandated by Part 69 shall establish and implement procedures to facilitate the birthing center's compliance with regulatory requirement for reporting results no later than 12 hours after initial specimen collection.</p>	
HIV 17	<p>HIV Standard 17</p> <p>Whenever a preliminary result is released, the laboratory report and all communication or recording of such a result shall clearly indicate that the positive finding is preliminary and that a supplemental report obtained through confirmatory testing will follow.</p>	<p>Facilities performing on-site testing may use physician-specific blanket authorizations to release preliminary HIV test results from perinatal HIV testing ordered under that practitioner's authority. Reference laboratories providing testing services to birthing facilities may also accept such blanket authorizations provided specifics of such arrangements are included in a written contract for laboratory services.</p> <p>Laboratory reports of preliminary results should specify the testing method(s) and contain or be accompanied by data on test performance characteristics, including, but not limited to, sensitivity and specificity of the test procedure to enable clinicians to make informed medical decisions. Laboratories should include, as part of the report, the statement "This preliminary result should be used in conjunction with clinical history, including maternal HIV risk factors, in determining a woman/infant's need to initiate zidovudine prophylaxis."</p> <p>Laboratories are encouraged to perform, or arrange for the performance of, two different screening test methods as a means of increasing the PPV of preliminary results.</p>

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HIV 18	<p>HIV Standard 18</p> <p>Confirmatory testing by Western blot or IFA shall be conducted on all specimens with a preliminary (unconfirmed) HIV positive result within 4 days of reporting the preliminary result or four days of specimen receipt for confirmatory testing.</p>	
	HIV RESISTANCE TESTING	
HIV19a HIV19b	<p>HIV Standard 19</p> <p>In addition to requirements found elsewhere in the NYS Laboratory Standards, reports for HIV resistance testing shall include:</p> <p>a) the name of the manufacturer and the testing methodology used; and,</p> <p>b) a statement indicating that results obtained with different assay methods or interpretation tools should not be used interchangeably.</p>	<p>The original manufacturer's report form should be used for reporting patient results. The laboratory should either include its name on the manufacturer's report or use a cover sheet to indicate the laboratory's name. If the laboratory chooses to use their laboratory information system to report results, the report form should contain the name of the testing method, and manufacturer, if applicable.</p> <p>The available resistance test methods differ at the level of technique and interpretation. Different test methods may be used clinically in support of one another, but it should be noted that the results from different test methods may provide different resistance interpretations. A statement to indicate this should appear on the report, or as an addendum to the report.</p>
	GENOTYPE METHODS	

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HIV20	<p>HIV Standard 20</p> <p>The laboratory shall have a process in place to ensure that the sequence at all resistance-associated codon positions is reviewed and verified.</p>	<p>Review and verification shall be performed by either : Validated software and trained personnel; or an operator and a reviewer with appropriate training when computer interpretative software is not used. Both the operator and reviewer must demonstrate appropriate training and evidence of competence.</p>
HIV21	<p>HIV Standard 21</p>	<p>Standard deleted.</p>
HIV22	<p>HIV Standard 22</p> <p>As part of compliance with Quality Assurance Standard 8, verification of proficiency for sequencing-based genotype assays must be established by measuring sequence concordance at the nucleotide level; and the amino acid level.</p>	<p>In cases where an external proficiency testing program monitors only amino acid-level accuracy, an internal test of nucleotide-level accuracy may be performed. Sufficient nucleotide-level accuracy is defined as 99% concordance for each sample tested, unless justification is documented.</p>