Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D0101031	02/06/2020
Name of Provider or Supplier	**Street Address, City, State**	
Danbury Hosp Dept Of Lab Med	24 Hospital Ave, Danbury, CT	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to retain patient test records to include instrument printouts for at least 2 years in the specialty of diagnostic immunology. Findings include: 1. Review on 1/22/2020 of a file provided by the laboratory containing records for positive HIV patient #1 collected on 1/18/19 at 15:18 and run on the BioRad BioPlex 2200 instrument revealed, the laboratory did not have the instrument printout for this patient. 2. Record review on 1/27/2020 of the BioPlex 2200 Instrument summary report printed on 1/24/2020 at 17:35 with a date range of 1/18/19 through 1/21/19 revealed: a. The report did not contain the unique patient identifier assigned to each patient. b. The report contained Human Immunodeficiency Virus (HIV) Ag-Ab, Syphilis and Rubella results. 3. Staff interview with the immunology general supervisor (GS) on 1/27/2020 at 10:50 AM confirmed the above findings. The GS stated a representative from BioRad archived all instrument results from 1/1/18 through 1/31/19 and did not retain the unique patient identifier with the results. The GS further stated this is the case for all tests performed by the laboratory on the BioPlex 2200 during this time period, to include Antinuclear Antibody (ANA), Anti-Cyclic Citrullinated Peptide (CCP), Cytomegalovirus, Toxoplasmosis IgG and IgM, Epstein-Barr Virus (EBV), HIV Ag-Ab, Measles, Mumps, Rubella, Varicella, Syphilis Total and Rapid Plasma Reagin (RPR), Vasculitis Myloperoxidase (MPO), Proteinase 3 (PR3), and Glomerular Basement Membrane (GBM).
D5014	GENERAL IMMUNOLOGY

	CFR(s): 493.1208 If the laboratory provides services in the subspecialty of General immunology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on record review and staff interview, the immunology laboratory failed to meet the requirements in 493.1230 through 493.1256, and 493.1281 through 493.1299. The cumulative effect of these systemic problems resulted in the laboratory's inability to ensure the accuracy and reliability of patient test results. Refer to D5205, D5207, D5291, D5311, D5403, D5407, D5409, D5411, and D5807.
D5205	COMPLAINT INVESTIGATIONS CFR(s): 493.1233 The laboratory must have a system in place to ensure that it documents all complaints and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate. This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory failed to have a system in place to investigate and document complaints and problems reported to the laboratory. Findings include: 1. During staff interview with the immunology general supervisor (GS) on 1/21/2020 at 9:30 AM, surveyor requested results of a complaint investigation (C1) received by the Connecticut Department of Public Health concerning incorrect and delayed reporting of HIV results, specimen collection requirements and storage conditions. The GS stated he/she was aware of the problem but did not have documentation concerning this investigation. 2. Record review on 1 /22/2020 of the laboratory's 'Quality Plan' revealed, the plan did not contain a system to investigate and document complaints and problems reported to the laboratory. 3. Record review on 1/27/2020 of the GS's handwritten document entitled, 'CT State Inspection 1/21/2020 - 1/22/2020 HIV Increase Reactivity Summary' revealed: a. A notation regarding a 3/5/19 field action report received from Bio-Rad, "Bulletin increase HIV reactivity." b. A meeting with a provider to discuss positive HIV numbers, complaint investigation (C2). 4. Record review on 1/27/2020 of the 'US Field Action Increased Reactivity for BioPlex 2200 HIV Ag-AB Kit Lot No. 300-868' report revealed: a. An increase level of reactivity with the BioPlex 2200 for lot number 300-868. b. Request to immediately discontinue use and dispose of any unused product. c. Documentation of 3 kits destroyed. 5. Staff interview with the GS regarding C2 on 1/27/2020 at 1:30 PM: a. Confirmed the laboratory does not have a procedure to ensure documentation of all complaints. b. The GS stated most of the investigation into the increase in positive HIV results was done verbally with Biorad field technical personnel and the laboratory did not receive written documentation as to suggestions on troubleshooting the above problem. c. The GS's notes were the only documentation/investigation other than the product recall that he/she had regarding the above increase in positive HIV testing. The above summary was compiled from various notes by the GS for surveyor review on 1/22/2020.
D5207	COMMUNICATIONS CFR(s): 493.1234

The laboratory must have a system in place to identify and document problems that occur as a result of a breakdown in communication between the laboratory and an authorized person who orders or receives test results.

This STANDARD is not met as evidenced by:
Based on record review and staff interview, the laboratory failed to identify and document problems with communicating reactive Human Immunodeficiency Virus (HIV) Antigen (Ag) Antibody (Ab) screen results and ensure the required confirmatory supplemental testing was completed or properly communicated to the provider in the subspecialty of general immunology. Findings include: 1. Record review on 1/22/2020 of the 'Danbury Hospital Department of Pathology & Laboratory Medicine Technically Speaking July 2016: Vol. 10, No 5' provider bulletin revealed: a. A test reporting table describing various scenarios of test results for HIV-1 p24 Ag, Anti HIV-1 or Anti HIV-2 with corresponding interpretations and required supplemental testing. b. The CDC flowchart for the recommended laboratory HIV testing algorithm. c. The table and flowchart do not correlate. 2. Record review on 1 /28/2020 of BioPlex HIV Ag-Ab assay reactive patient results revealed the following were not tested as required by the CDC guidelines: a. 7 of 25 reactive HIV-1 or HIV-2 antibody BioPlex specimens in 2018 did not have confirmatory nucleic acid test (NAT) testing performed when the HIV-1/HIV-2 antibody differentiation immunoassay results were negative. b. 5 of 25 reactive HIV p24 Ag BioPlex specimens in 2018 did not have the HIV-1/HIV-2 antibody differentiation immunoassay performed. c. 1 of 36 reactive HIV-1 or HIV-2 antibody BioPlex specimens in 2019 did not have confirmatory NAT testing performed when the HIV-1 /HIV-2 antibody differentiation immunoassay results were negative. d. 4 of 36 reactive HIV p24 antigen BioPlex specimens in 2019 did not have the HIV-1/HIV-2 antibody differentiation immunoassay performed. 3. Record review on 1/21/2020 of the laboratory 'Critical Tests in the Clinical Laboratory - Network AD.5.8.2' revealed: a. "Critical test results must be communicated to a physician or other clinical personnel responsible for the patient's care as quickly as possible, following uniform procedures that ensure prompt, accurate and effective communication." b. "Laboratory personnel will communicate critical test results by telephone call as soon as feasible (generally within 30 minutes) to a physician or other clinical personnel responsible for the patient's care." c. "The caller must document the notification and read-back in the laboratory information system (LIS) or other permanent document." d. "HIV inc. occupational exposure and Labor and Delivery" is listed as a critical test. 4. Record review of Patient #2 HIV Ag -Ab reactive test results on 1/27/2020 revealed: a. Reactive HIV Ag Ab screen was confirmed and called to provider on 8/2/18. b. HIV differentiation test auto verified from reference laboratory on 8/6/18. c. HIV Ag-Ab screen was resulted in the LIS on 8/6/18. d. Provider notification of the differentiation test result was called on 8/15/18. 5. Record review on 1/28/2020 of the 2018 and 2019 BioPlex HIV Ag-Ab assay reactive patient results revealed the laboratory policy for provider notification of critical test results was not followed: a. 8 of 25 reactive HIV Ag-Ab assay results in 2018. b. 13 of 36 reactive HIV Ag-Ab assay results in 2019. 6. Record review on 1/28/2020 of an email dated 2/28/19 from the immunology general supervisor (GS) to laboratory staff revealed: a. "Providers may be called by immunology staff to collect additional blood for HIV confirmation." b. Each test requires one full lavender top tube. c. Order as a miscellaneous send out (Mayo HVDIP, Mayo HIVQN) d. The confirmation tests are not built in the LIS. 7. Record review on 1/28/2020 of 2019 BioPlex HIV Ag-Ab reactive patient results follow-up confirmatory testing revealed: a. The laboratory did not have documentation of

	confirmatory testing for 6 of 36 Reactive HIV Ag Ab screen results. b. 3 of 36 reactive HIV Ag Ab screen results had the wrong confirmatory tests ordered and reported. 8. Record review on 1/28/2020 of the Mayo Clinic collection instructions for the HIV Ab Confirm/Differentiation (HVDIP) and HIV-1 RNA Detection and Quantification, Plasma (HIVQN) tests revealed, "Centrifuge blood collection tube and aliquot plasma into plastic vial per collection tube manufacturer's instructions (eg, centrifuge and aliquot within 2 hours of collection for BD Vacutainer tubes)." 9. Staff interview with the immunology general supervisor (GS) on 1/27/2020 at 11:00 AM revealed: a. Provider notification of change in specimen type for the confirmatory testing did not occur. b. Additional sample(s) are requested along with the appropriate Mayo order code when a reactive screen result is called to the provider. c. GS was not aware of the stability requirement of 2 hours for the HVDIP or HIVQN tests. d. The required confirmatory HIV testing is entered into the LIS as a miscellaneous test code by laboratory personnel. This leads to errors in the correct supplemental tests being performed if ordered by the provider incorrectly. e. Confirmatory testing results auto-verify from Mayo Clinic in the LIS, therefore GS manually monitors send out results and enters the HIV Ag-Ab screen reactive result when time allows. This may occur days later. 10. Staff interview with the operations manager (OM) on 1/27/2020 at 10: 22 AM confirmed the findings in 4, 5 and 6 above. OM did not know why the 9 day delay of provider notification occurred. 11. Staff interview with the technical supervisor (TS) on 1/28/2020 at 9:00 AM confirmed the findings in 1, 2 and 3 above. He/she stated the laboratory test is 5th generation and can do step two of the CDC guidelines. Upon further review of the above documents, TS concluded the laboratory had been following the Technically Speaking table which is incorrect. 12. The laboratory performed 7,418 HIV Ag-Ab tests in 2018 and 7,792 tests in 2019.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess, and correct problems associated with Human Immunodeficiency Virus (HIV) testing in the subspecialty of diagnostic immunology. Findings include: 1. Record review on 1/22 /2020 of the laboratory's 'Quality Plan' revealed: a. Section 2B: Personnel Training and Development, "Training is also provided when new procedures are being implemented and when procedures are changed." b. Section 5A: Development and Use of Standard Operation Procedures, "New procedures or those with major revisions require Medical Director or designee signature before they are implemented." c. Section 5I: Communication of Critical Results, "Criteria are in place for the release of laboratory results and procedures for immediate notification of the ordering physician (including read back) when results of certain tests fall into established 'alert' or 'critical' ranges." d. Section 5K: Record Retention, "Records including test orders, patient result reports, retired procedures or older versions of procedures are kept in accordance with licensing agency standards." e. Section 7: Performance Improvement, "Based on the examination of pre-analytical, analytical and post-analytical processes, data is evaluated to determine whether opportunities for

	the improvement of laboratory processes exist." f. Section 7A: Deviations/Adverse Events and Corrective Action, "Events and resolution of events are reported at the monthly PI meeting." g. Section 7C: Quality Monitoring/Performance Improvement, "Policies, processes and procedures are in place to continuously improve the operational processes and quality management system in pre-analytic, analytic and post-analytic phases. Data is shared with departments outside the laboratory as appropriate and at the Hospital PI meetings. Example of monitored areas include: investigation of product recalls, market withdrawals, episodes, complaints, deviations, etc." h. Section 11: Non-Conformance, "The procedure to be implemented when it detects that a non-conformance shall ensure that: i. The results of nonconforming examinations already released are recalled or appropriately identified if necessary. ii. Laboratory management shall document and implement any changes required to its operational procedures resulting from non-conformance investigations." 2. Staff interview on 1/28/2020 at 1:00 PM with the immunology general supervisor (GS): a. Confirmed the laboratory does not always document employee training or education when changes in procedures occur. b. Stated the HIV procedure changes frequently depending on who is complaining. The procedure is not always updated to reflect the most recent and updated policy, therefore the laboratory director's signature is not always on the most current procedure. c. The GS was confused concerning the BioPlex HIV procedure signature page. GS wasn't sure if the correct information is included beside the revision date and the signature date. Information on what was revised was not always clear. d. Confirmed critical HIV screening results are not always called according to the above policy. The GS stated that results can also be emailed to providers and sometimes the results are called days later or not at all. When confirmatory results are received they autoverify in the LIS. The screening results do not autoverify after the confirmatory results autoverify. Testing personnel do not enter results because the results are often entered incorrectly. The GS manually monitors for confirmatory test results completion and then results the preliminary screen in the LIS when he/she has time. In addition, callers do not always get the name of the person spoken to. e. The laboratory does not have Bioplex instrument printouts with patient identifiers from 1/1/18 to 1/31/19 as they were de-identified during archive by the manufacturer. f. The GS received the technical bulletin noted above on 3/5/19, but it was not discussed at the laboratory core lab meeting until 6/6 /19. GS notes, read, "HIV increased reactivity - spin samples." The GS stated the laboratory does not have official minutes from the core lab meetings, therefore notes are relied upon. The GS stated he/she double spins, but is not sure if any other testing personnel do it. Double spinning SST tubes is not addressed in the procedure. g. GS did not have an investigative file for the complaint concerning HIV results with C2. GS had notes in several places and did not have written documentation from the manufacturer for visits made to address the complaint. h. The procedure contains incorrect information concerning confirmatory testing. The procedure does not contain the required confirmatory testing as published by the CDC. The specimens are not sent out for Western Blot testing as indicated. The GS was told by the technical supervisor that their test was a 5th generation and therefore could suffice as a step 2 screening test by the CDC guidelines. i. The procedure does not contain the requirement to spin, separate and freeze the sample within 2 hours of collection. The GS stated he/she was unaware of this requirement. j. The samples are not automatically sent out for confirmatory testing as indicated in the procedure because confirmatory testing requires EDTA plasma and patients must be redrawn. 8. Staff interview with the Hospital Director of Quality on 1/22/2020 at 11:40 AM stated the 2019 meeting minutes of the hospital wide Quality Improvement Committee did not contain any laboratory quality data during the year.

D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory failed to ensure appropriate testing, processing and storage of patient samples to ensure stability and accuracy of results for Human Immunodeficiency Virus (HIV) confirmatory testing. Findings include: 1. Record review on 1/28/2020 of the Mayo Clinic collection instructions for the HIV AB Confirmation/Differentiation, Plasma and the HIV-1 RNA Detection and Quantification, Plasma test revealed, "Centrifuge blood collection tube per collection tube manufacturer's instruction (eg, centrifuge and aliquot within 2 hours of collection for BD Vacutainer tubes). Transfer plasma into aliquot tubes." 2. Record review on 1 /28/2020 of an email dated 2/28/19 from the immunology general supervisor (GS) to laboratory staff revealed: a. "Providers may be called by immunology staff to collect additional blood for HIV confirmation." b. Each test requires one full lavender top tube. c. Order as a miscellaneous send out (Mayo HVDIP, Mayo HIVQN) d. The confirmation tests are not built in the LIS. 3. Record review on 1/28/2020 of the laboratory's, Biorad BioPLex 2200 Analyzer Procedure, Section 8, CC-BP.1, Reference Range and Interpretations' revealed: a. Supplemental testing requires the patient to be redrawn for one full EDTA tube for each supplemental test. The EDTA tubes are spun down and the plasma aliquoted and frozen. b. A time limit in which the specimens must be spun, aliquoted and frozen is not specified. 4. Record review on 1 /28/2020 of the collection and receipt records for 11 BioPlex 2200 reactive patients revealed: a. Confirmatory testing requires an additional blood collection of EDTA plasma. b. 6 of the 11 above specimens exceeded the 2 hour time limit required by the reference laboratory for testing. 5. Staff interview with the send out supervisor (SOS), GS and laboratory operations manager on 1/28/2020 at 12:30 PM confirmed the above findings. The SOS and GS stated they did not realize there was a time limit on when the specimens must be spun down and frozen.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals

	(normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory failed to provide a complete procedure manual for Human Immunodeficiency Virus (HIV) testing in the subspecialty of general immunology. Findings include: 1. Record review of laboratory's Bio-Rad BioPlex 2200 analyzer procedure manual on 1/22/2020 revealed the HIV procedure lacked the following required elements: a. Specimen stability requirements for referral confirmatory HIV samples. b. Proper interpretation of results according to CDC guidelines. c. System of when and how to enter patient HIV test results in the Cerner laboratory information system. d. Protocol for provider notification and documentation of critical/reactive HIV test results. e. Proper ordering of confirmatory diagnostic testing according to CDC guidelines. 2. Staff interview with the immunology general supervisor (GS) on 1/27/2020 at 1:55 PM confirmed the above findings. GS stated: a. Results of the reactive HIV screens are either called or emailed and the email protocol is not in the procedure. b. Staff do not inform the provider to order the required CDC Step 2 supplemental HIV 1 & 2 Antibody testing when the p24 Antigen is reactive. c. The reactive HIV screen results are only entered after the supplemental HIV results have been reported and this manual process is not defined in the procedure.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory director failed to approve, sign and date laboratory procedures prior to being placed into use in the subspecialty of general immunology. Findings include: 1. Record review on 1/28/2020 of the laboratory's 'BioRad Bioplex 2200 Analyzer' policy signed and approved by the laboratory director on 6/16/19, revealed the following current practices are not included: a. Section 2: Specimen Collection and Handling, does not mention double spinning SST tubes. b. Section 8: Reference Range and interpretation: i. Human Immunodeficiency Virus (HIV) screen results do not autoverify. They are manually entered. ii. Email provider notification is not addressed. 2. Staff interview on 1/28 /2020 at 1:00 PM with the immunology general supervisor (GS) confirmed the above findings. The GS stated the HIV procedure changes frequently depending on who is complaining. The procedure is not always updated to reflect the most recent and updated policy, therefore the laboratory director's signature is not always on the most current procedure.
D5409	PROCEDURE MANUAL CFR(s): 493.1251(e) The laboratory must maintain a copy of each procedure with the dates of initial use

	and discontinuance as described in 493.1105(a)(2). This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to maintain all versions of the BioPlex 2200 Analyzer test procedure in the specialty of Diagnostic Immunology. Findings include: 1. Record review of the Danbury Hospital Document Control Log on 1/28/2020 revealed: a. Procedure Number CC-BP.1. b. Title: BioRad Bioplex 2200 Analyzer c. Original/Master copy effective date: 6/27/13. d. Record of procedural changes as follows: 11/19/13, 3/27/15, 4/2016, 2/5/19, 5/15/19 and 1/27 /2020. 2. Record review on 1/28/2020 of the procedure records for the BioRad BioPlex 2200 Analyzer CC-BP.1 revealed the laboratory does not have the original /master procedure (6/27/13) and the first two revisions of the procedure (11/19/13 and 3/27/15). 3. Staff interview with the immunology general supervisor on 1/28/2020 at 9: 45 AM confirmed the above findings.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to follow manufacturer's instructions for patient sample confirmatory testing for Human Immunodeficiency Virus (HIV) in the subspecialty of general immunology. Findings include: 1. Record review of the 'Bio-Rad BioPlex 2200 system HIV Ag-Ab Instructions for Use' on 1/22/2020 revealed: "Initially reactive specimens must be retested in duplicate. If they are repeatedly reactive, they must be investigated by additional, more specific, or supplemental tests. Refer to CDC guidelines for the current recommended HIV testing algorithm." 2. Record review on 1/28/2020 of BioPlex HIV Ag-Ab assay reactive patient results revealed the following were not tested as required by the CDC guidelines: a. 7 of 25 reactive HIV-1 or HIV-2 antibody BioPlex specimens in 2018 did not have confirmatory nucleic acid test (NAT) testing performed when the HIV-1/HIV-2 antibody differentiation immunoassay results were negative. b. 5 of 25 reactive HIV p24 Ag BioPlex specimens in 2018 did not have the HIV-1/HIV-2 antibody differentiation immunoassay performed. c. 1 of 36 reactive HIV-1 or HIV-2 antibody BioPlex specimens in 2019 did not have confirmatory NAT testing performed when the HIV-1/HIV-2 antibody differentiation immunoassay results were negative. d. 4 of 36 reactive HIV p24 antigen BioPlex specimens in 2019 did not have the HIV-1/HIV-2 antibody differentiation immunoassay performed. 3. Staff interview with the technical supervisor (TS) on 1/28/2020 at 9:00 AM confirmed the above findings. He/she stated the laboratory test is 5th generation and can do step two of the CDC guidelines. Upon further review of the above documents, TS concluded the laboratory did not follow the manufacturer instructions for confirmatory testing. 4. The laboratory performed 7,418 HIV Ag-Ab tests in 2018 and 7,792 tests in 2019.
D5807	TEST REPORT CFR(s): 493.1291(d)

	Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory failed to ensure the correct result interpretation appears on the final test report. Findings include: 1. Record review on 1/28/2020 of the CDC guideline 'Recommended Laboratory HIV testing Algorithm for Serum or Plasma Specimens, Updated January 2018' revealed: a. Specimens with a reactive/repeatedly reactive antigen/antibody immunoassay should be tested with an FDA-approved supplemental antibody immunoassay that differentiates HIV-1 antibodies from HIV-2 antibodies. b. Specimens with a reactive on the initial HIV antigen (Ag) /antibody (Ab) immunoassay and non-reactive or indeterminate on the HIV-1/HIV-2 antibody differentiation immunoassay should be tested with an FDA-approved HIV-1 Nucleic acid test (NAT). 2. Record review on 1 /28/2020 of final test reports for patients with reactive Human Immunodeficiency Virus (HIV) -1 p24 Antigen tests and nonreactive HIV-1 and HIV-2 antibodies revealed: a. The reports had the following result interpretation, "A test is preliminary positive for HIV-1 p24 antigen in the absence of reactivity for HIV-1 or HIV-2 antibodies may indicate an acute HIV-1 infection. Result is not diagnostic, and the diagnosis of HIV infection should be made based on the results of an HIV-1 RNA quantification test." b. In 2018, 4 of 4 patients had the above incorrect interpretation on their test report and did not have the required supplemental testing performed. c. In 2019, 6 of 6 patients had the above incorrect interpretation on their test report and did not have the required supplemental testing performed. d. The report interpretation does not request the appropriate follow-up testing as defined in 1a above. 3. Staff interview with the technical supervisor (TS) on 1/28/2020 at 9:00 AM confirmed the above findings. He/she stated the laboratory test is 5th generation and can do step two of the CDC guidelines. Upon further review of the above documents, TS concluded the laboratory had been following the incorrect protocol.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on record review and staff interview, the laboratory director failed to provide overall management and direction in accordance with 493.1445. The cumulative effect of this lack of oversight resulted in the laboratory director's inability to ensure the accuracy and reliability of patient test results in the subspecialty of general immunology. 1. The laboratory director failed to ensure technical supervisor duties are properly performed. Refer to D6079. 2. The laboratory director failed to ensure testing systems developed and used by the laboratory provide quality services for all aspect of test performance. Refer to D6082. 3. The laboratory director failed to ensure an up to date laboratory procedure manual is available to and followed by laboratory personnel. The laboratory director failed to ensure manufacturer's instructions were followed by testing personnel including adequate processing of referral specimens.

	Refer to D6087. 4. The laboratory director failed to ensure that quality assessment programs are established and maintained to ensure the quality of laboratory services provided and to identify failures in quality as they occur. Refer to D6094. 5. The laboratory director failed to ensure that reports of test results include pertinent information required for interpretation. Refer to D6098. 6. The laboratory director failed to approve and sign new and/or revised procedures prior to patient testing. Refer to D6106.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Refer to D3031, D5205, D5207, D5291, D5311, D5403, D5407, D5409, D5411, D5807 and D6112.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. This STANDARD is not met as evidenced by: Refer to D5291, D5407, D5411 and D5807.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Refer to D5311, D5403, D5407 and D5411.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are

	established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Refer to D5205, D5207 and D5291.
D6098	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(8) The laboratory director must ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Refer to D5807.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Refer to D5407.
D6112	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451 The technical supervisor is responsible for the technical and scientific oversight of the laboratory. The technical supervisor is not required to be on site at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide supervision as specified in (a) of this section. This STANDARD is not met as evidenced by: Refer to D5207 and D5411.