Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0965332	08/01/2023
Name of Provider or Supplier	**Street Address, City, State**	
Bio-Tech Clinical Laboratories Inc	9000 Nw 15th St Unit 1, Doral, FL	

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
D0000	An unannounced complaint survey for #2023000754 was conducted from 01/30/2023 through 08/01/2023. The allegations were substantiated, no deficiencies were cited.
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on review of the test menu and proficiency testing (PT) records, and interview, the laboratory failed to enroll in an approved PT program for the three analytes in 2021 and 2022. Findings included: Review of the test menu provided with Clinical Laboratory Improvement Amendments (CLIA) Application for Certification indicated American Association of Bioanalysts (AAB) was the PT provider for the following analytes: Immunoglobulin (Ig) G, IgA, and IgM. Review of the PT records from AAB showed that there was no PT performed on IgG, IgA, and IgM. On 02/01/2023 at 4:25 PM, Testing Personnel A stated they were not doing PT on the above mentioned analytes.
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it

receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing.

This STANDARD is not met as evidenced by:
Based on review of American Association of Bioanalysts (AAB) proficiency testing (PT) records and the procedure manual, and interview, the laboratory failed to treat PT samples in the same manner as patients for five (2021 1st, 2nd, 3rd and 2022 1st, 2nd) of six (2021 1st, 2nd, 3rd and 2022 1st, 2nd, 3rd) testing events reviewed in the speciality of Hematology. Findings included: Review of the policy titled Reporting Results Using LIS (laboratory information system) noted the "results transmit automatically. On 04/12/2023 at 6:40 PM, Testing Personnel A stated the laboratory information system (LIS) reports patient results after testing personnel approved the results and that rerun patient specimens are reported from one set of results and does not combine results from the two separate runs. Results are reported out for the following analytes: Leukocytes, Erythrocytes, Hemoglobin, Hematocrit, Platelets, Neutrophil %, Lymphocyte %, Monocyte %, Eosinophil %, and Basophil %. Review of the hematology instrument printout and the AAB attestation with the test results that were reported revealed the follow discrepancies. 1. 2021 1st event 2021 1st event sample "Vial 2" Results reported to AAB for Platelets - 480 Results from instrument printout run on 02/15/2021 at 13:33:51 reported Platelets - 429 Results from instrument printout run on 02/15/2021 at 13:47:30 reported Platelets - 480 All other test results for 2021 1st event vial 2 were reported from the first run on 02/15/2021 at 13:33:51 . 2. 2021 2nd event 2021 2nd event sample "Vial 7" Results reported to AAB for Lymphocyte % - 18.5% Results from instrument printout run on 05/20/2021 at 12:10:37 reported Lymphocyte % - 19.6% Results from instrument printout run on 05/20/2021 at 12:28:25 reported Lymphocyte % - 18.0% No other instrument printouts were saved. 2021 2nd event sample "Vial 7" Results reported to AAB for Monocyte % - 8.0% Results from instrument printout run on 05/20/2021 at 12:10:37 reported Monocyte % - 5.6% Results from instrument printout run on 05/20/2021 at 12:28:25 reported Monocyte % - 8.5% No other instrument printouts were saved. All other test results for 2021 2nd event vial 7 were reported from the second run on 05/20 /2021 at 12:28:25. 2021 2nd event sample "Vial 9" Results reported to AAB for Erythrocytes - 4.14 Results from instrument printout run on 05/20/2021 at 12:20:21 reported Erythrocytes - 4.12 Results from instrument printout run on 05/20/2021 at 12: 38:11 reported Erythrocytes - 4.12 Results from instrument printout run on 05/25 /2021 at 10:36:36 reported Erythrocytes - 4.14 2021 2nd event sample "Vial 9" Results reported to AAB for Hemoglobin - 11.8 Results from instrument printout run on 05/20/2021 at 12:20:21 reported Hemoglobin - 11.8 Results from instrument printout run on 05/20/2021 at 12:38:11 reported Hemoglobin - 11.7 Results from instrument printout run on 05/25/2021 at 10:36:36 reported Hemoglobin - 11.8 2021 2nd event sample "Vial 9" Results reported to AAB for Hematocrit - 37.2 Results from instrument printout run on 05/20/2021 at 12:20:21 reported Hematocrit - 37.0 Results from instrument printout run on 05/20/2021 at 12:38:11 reported Hematocrit - 36.7 Results from instrument printout run on 05/25/2021 at 10:36:36 reported Hematocrit - 37.2 2021 2nd event sample "Vial 9" Results reported to AAB for Platelets - 300 Results from instrument printout run on 05/20/2021 at 12:20:21 reported Platelets - 296 Results from instrument printout run on 05/20/2021 at 12:38:

11 reported Platelets - 286 Results from instrument printout run on 05/25/2021 at 10:36:36 reported Platelets - 300 2021 2nd event sample "Vial 9" Results reported to AAB for Lymphocyte % - 28.3 Results from instrument printout run on 05/20/2021 at 12:20:21 reported Lymphocyte % - 25.3 Results from instrument printout run on 05/20/2021 at 12:38:11 reported Lymphocyte % - 26.8 Results from instrument printout run on 05/25/2021 at 10:36:36 reported Lymphocyte % - 26.8 No other instrument printouts were saved. 2021 2nd event sample "Vial 9" Results reported to AAB for Monocyte % - 4.9 Results from instrument printout run on 05/20/2021 at 12:20:21 reported Monocyte % - 7.4 Results from instrument printout run on 05/20/2021 at 12:38:11 reported Monocyte % - 6.4 Results from instrument printout run on 05/25/2021 at 10:36:36 reported Monocyte % - 4.9 All other test results for 2021 2nd event vial 9 were reported from the second run on 05/20/2023 at 12:38:11. 2021 2nd event sample "Vial 10" Results reported to AAB for Eosinophil % - 5.4 Results from instrument printout run on 05/20/2021 at 12:22:46 reported Eosinophil % - 5.4 Results from instrument printout run on 05/20/2021 at 12:36:19 reported Eosinophil % - 5.2 2021 2nd event sample "Vial 10" Results reported to AAB for Basophil % - 0.5 Results from instrument printout run on 05/20/2021 at 12:22:46 reported Basophil % - 0.3 Results from instrument printout run on 05/20/2021 at 12:36:19 reported Basophil % - 0.7 No other instrument printouts were saved. All other test results for 2021 2nd event vial 10 were reported from the second run on 05/20/2021 at 12:36:19. 3. 2021 3rd event 2021 3rd event sample "Vial 11" Results reported to AAB for Neutrophil % - 54.5 Results from instrument printout run on 09/23/2021 at 14:39:45 reported Neutrophil % - 50.5 No other instrument printouts were saved. 2021 3rd event sample "Vial 11" Results reported to AAB for Lymphocyte % - 33.3 Results from instrument printout run on 09/23/2021 at 14:39:45 reported Lymphocyte % - 39.3 No other instrument printouts were saved. 2021 3rd event sample "Vial 11" Results reported to AAB for Monocyte % - 4.0 Results from instrument printout run on 09/23/2021 at 14:39:45 reported Monocyte % - 2.0 No other instrument printouts were saved. All other test results for 2021 3rd event vial 11 were reported from 09/23/2021 at 14:39:45. 2021 3rd event sample "Vial 12" Results reported to AAB for Neutrophil % - 59.5 Results from instrument printout run on 09/20/2021 at 11:12:07 reported Neutrophil % - 59.1 No other instrument printouts were saved. 2021 3rd event sample "Vial 12" Results reported to AAB for Lymphocyte % - 28.2 Results from instrument printout run on 09/20/2021 at 11:12:07 reported Lymphocyte % - 26.2 No other instrument printouts were saved. 2021 3rd event sample "Vial 12" Results reported to AAB for Monocyte % - 5.8 Results from instrument printout run on 09/20/2021 at 11:12:07 reported Monocyte % - 7.0 No other instrument printouts were saved. 2021 3rd event sample "Vial 12" Results reported to AAB for Eosinophil % - 6.2 Results from instrument printout run on 09/20/2021 at 11:12:07 reported Eosinophil % - 6.8 No other instrument printouts were saved. 2021 3rd event sample "Vial 12" Results reported to AAB for Basophil % - 0.3 Results from instrument printout run on 09/20/2021 at 11:12:07 reported Basophil % - 0.9 No other instrument printouts were saved. All other test results for 2021 3rd event vial 12 were reported from 09/20/2021 at 11:12:07. 2021 3rd event sample "Vial 14" Results reported to AAB for Leukocytes (White Blood Cells - WBC) - 9.1 Results from instrument printout run on 09/20/2021 at 11:17:18 reported WBC - 9.4 Results from instrument printout run on 09/23/2021 at 14:35:50 reported WBC - 8.8 No other instrument printouts were saved. 2021 3rd event sample "Vial 14" Results reported to AAB for Neutrophil % - 58.8 Results from instrument printout run on 09/20/2021 at 11:17:18 reported Neutrophil % - 56.3 Results from instrument printout run on 09/23/2021 at 14:35:50 reported Neutrophil % - 58.2 No other instrument printouts were saved. 2021 3rd event sample "Vial 14" Results reported to AAB for Lymphocyte % - 30.2 Results from instrument printout run on 09/20/2021 at 11:17:18 reported Lymphocyte % - 30.5 Results from instrument

	printout run on 09/23/2021 at 14:35:50 reported Lymphocyte % - 30.2 2021 3rd event sample "Vial 14" Results reported to AAB for Monocyte % - 4.4 Results from instrument printout run on 09/20/2021 at 11:17:18 reported Monocyte % - 3.6 Results from instrument printout run on 09/23/2021 at 14:35:50 reported Monocyte % - 3.2 No other instrument printouts were saved. 2021 3rd event sample "Vial 14" Results reported to AAB for Eosinophil % - 6.0 Results from instrument printout run on 09/20 /2021 at 11:17:18 reported Eosinophil % - 8.8 Results from instrument printout run on 09/23/2021 at 14:35:50 reported Eosinophil % - 7.8 No other instrument printouts were saved. 2021 3rd event sample "Vial 14" Results reported to AAB for Basophil % - 0.6 Results from instrument printout run on 09/20/2021 at 11:17:18 reported Basophil % - 0.8 Results from instrument printout run on 09/23/2021 at 14:35:50 reported Basophil % - 0.6 All other test results for 2021 3rd event vial 14 were reported from 09/20/2021 at 11:17:18. 2021 3rd event sample "Vial 15" Results reported to AAB for Leukocytes - 3.5 Results from instrument printout run on 09/23 /2021 at 14:37:32 reported WBC - 3.4 No other instrument printouts were saved. 2021 3rd event sample "Vial 15" Results reported to AAB for Neutrophil % - 53.8 Results from instrument printout run on 09/23/2021 at 14:37:32 reported Neutrophil % - 51.8 No other instrument printouts were saved. 2021 3rd event sample "Vial 15" Results reported to AAB for Lymphocyte % - 34.4 Results from instrument printout run on 09 /23/2021 at 14:37:32 reported Lymphocyte % - 38.0 No other instrument printouts were saved. 2021 3rd event sample "Vial 15" Results reported to AAB for Monocyte % - 3.9 Results from instrument printout run on 09/23/2021 at 14:37:32 reported Monocyte % - 1.9 No other instrument printouts were saved. 2021 3rd event sample "Vial 15" Results reported to AAB for Eosinophil % - 7.6 Results from instrument printout run on 09/23/2021 at 14:37:32 reported Eosinophil % - 7.7 No other instrument printouts were saved. 2021 3rd event sample "Vial 15" Results reported to AAB for Basophil % - 0.3 Results from instrument printout run on 09/23/2021 at 14: 37:32 reported Basophil % - 0.6 No other instrument printouts were saved. All other test results for 2021 3rd event "Vial 15" were reported from 09/23/2021 at 14:37:32. 4. 2022 1st event 2022 1st event sample "Vial 1"through "Vial 5" Results reported to AAB came from two laboratories, Lab A and Lab B (a sister lab that has their own Clinical Laboratory Improvement Amendments (CLIA) Certificate of Accreditation) Results that were reported from Lab A instrument printouts on 02/11/2022 for Leukocytes, Erythrocytes, Hemoglobin, Hematocrit, and Platelet Count Results that were reported from Lab B instrument printouts on 02/16/2022 for Neutrophil %, Lymphocyte %, Monocyte %, Eosinophil %, and Basophil %. 5. 2022 2nd event 2022 2nd event sample "Vial 6" to Vial 10" Results reported to AAB from instrument printout run on 05/20/2022 for Leukocytes, Erythrocytes, Hemoglobin, Hematocrit, and Platelet Count No other instrument printouts were saved. Results reported to AAB for Neutrophil %, Lymphocyte %, Monocyte %, Eosinophil %, and Basophil % where hand written on the instrument printout dated 05/20/2022. On 02/01/2023 at 11:00 AM, Testing Personnel A stated that they may have rerun some samples and then threw away the printouts. On 02/01/2023 at 11:11 AM, Testing Personnel A stated that the 2022 1st event must have been run over there (Lab B). On 02/01/2023 at 11: 30 AM, Testing Personnel A verified that the oldest records stored in the hematology instruments memory was from 11/17/2022 and that they don't backup the data on the instrument.
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the

	laboratory's routine methods This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and interview, the laboratory failed to have all testing personnel rotate through PT samples for PT in the specialties of Diagnostic Immunology, Chemistry and Hematology for six of six (2021 1st, 2nd, 3rd, and 2022 1st, 2nd, 3rd) events. Findings included: Review of the Laboratory Personnel Report, signed and dated by the Laboratory Director on 1/30/2023, listed five testing personnel. Testing Personnel (TP) A, B, D, and E all worked in the first floor laboratory (Diagnostic Immunology, Chemistry, and Hematology) and TP-C is the only TP who works in the second floor laboratory (Microbiology). Review of the policy titled "Proficiency Testing" noted "The educational purpose and documentation of proficiency is best served by a rotation that allows involvement of all technologists in the proficiency testing program." 1. Review of the proficiency testing records from American Association of Bioanalysts (AAB) showed that each PT event was performed by one to three testing personnel . Proficiency testing for Blood Cell Identification, Cardiac Markers / Isoenzymes, Hematology with Diff C, Hepatitis Markers, and HIV Markers, was performed by TP-A for six of six events (2021 1st, 2nd, 3rd, and 2022 1st, 2nd, 3rd). Proficiency testing for Antinuclear Antibody, Antistreptolysin O, Basic Chemistry, Infectious Mononucleosis, and Rubella, was performed by TP-B for six of six events (2021 1st, 2nd, 3rd, and 2022 1st, 2nd, 3rd). Proficiency testing for Coagulation was performed by TP-A for five (2021 1st, 2nd, and 2022 1st, 2nd, 3rd) of six events (2021 1st, 2nd, 3rd, and 2022 1st, 2nd, 3rd) and by TP-E for three (2021 1st, 3rd, and 2022 2nd) of six events (2021 1st, 2nd, 3rd, and 2022 1st, 2nd, 3rd). Proficiency testing for Comprehensive Chemistry was performed by TP-A for three (2021 1st, 3rd, and 2022 2nd) of six events (2021 1st, 2nd, 3rd, and 2022 1st, 2nd, 3rd) and by TP-B for six of six events (2021 1st, 2nd, 3rd, and 2022 1st, 2nd, 3rd). Proficiency testing for Therapeutic Drugs was performed by TP-A for five (2021 1st, 3rd, and 2022 1st, 2nd 3rd) of six events (2021 1st, 2nd, 3rd, and 2022 1st, 2nd, 3rd), and by TP-B for six of six events (2021 1st, 2nd, 3rd, and 2022 1st, 2nd, 3rd). 2. Review of the proficiency testing records from College of American Pathologists (CAP) showed that each PT event was performed by one testing personnel . Proficiency testing for Mycobacterium Tuberculosis was performed by TP-B for four of four events (2021 1st, 2nd, and 2022 1st, 2nd). 3. On 02/01/2022 at 10: 24 AM, Testing Personnel A acknowledged they did not rotate the performance of PT testing amongst all testing personnel.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and interview, the Laboratory Director and the Testing Personnel failed to sign the attestation form for PT in the specialties of Chemistry, Diagnostic Immunology Hematology, and Microbiology for 6 of 6 (2021 1st, 2nd, 3rd, 2022 1st, 2nd, 3rd) testing events. Findings included: Review of the policy titled "Proficiency Testing" noted "PT result is reviewed by the Medical Director upon report submission and the attestation letter must be signed."

	The American Association of Bioanalysts (AAB) attestation form states "In addition to the analysts' signature, one of the following must sign once for all analytes reported on this form. Director or Technical Consultant (moderate complexity) or Technical Supervisor (high complexity)." The College of American Pathologists (CAP) stated "the individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient work load using the laboratory's routine methods. The laboratory director or designee and the testing personnel must sign on the results form." 1. Review of the AAB PT records showed the attestation statements were not signed by the Laboratory Director for the following: 2022 1st event for Basic Chemistry, Hematology with Diff C, and Therapeutic Drugs. 2022 2nd event for Antinuclear Antibody, Antistreptolysin O, Bacteriology, Basic Chemistry, Blood Cell Identification, Cardiac Markers / Isoenzymes, Coagulation, Comprehensive Chemistry, Hematology with Diff C, Hepatitis Markers, HIV (Human Immunodeficiency Virus) Markers, Infectious Mononucleosis, Rubella, Syphilis Serology, and Therapeutic Drugs. 2022 3rd event for Comprehensive Chemistry and HIV Markers. 2. Review of the AAB PT records showed the attestation statements were not signed by the Testing Personnel for the following: 2022 3rd event for Bacteriology, Hepatitis Markers, HIV Markers, and Parasitology. 3. On 02/01/2023 at 10:35 AM, the Testing Personnel A acknowledged that not all the attestations were not signed by the Laboratory Director or the testing personnel.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and interview, the laboratory failed to retain the Hematology instrument printout when they reran PT samples for two (2021 3rd, 2022 2nd) of six (2021 1st, 2nd, 3rd, and 2022 1st, 2nd, 3rd) events. Findings included: 2021 3rd event sample "Vial 11" Results reported to AAB for Neutrophil % - 54.5 Results from instrument printout run on 09/23/2021 at 14:39:45 reported Neutrophil % - 50.5 No other instrument printouts were saved. 2021 3rd event sample "Vial 11" Results reported to AAB for Lymphocyte % - 33.3 Results from instrument printout run on 09/23/2021 at 14:39:45 reported Lymphocyte % - 39.3 No other instrument printouts were saved. 2021 3rd event sample "Vial 11" Results reported to AAB for Monocyte % - 4.0 Results from instrument printout run on 09/23/2021 at 14:39:45 reported Monocyte % - 2.0 No other instrument printouts were saved. 2021 3rd event sample "Vial 12" Results reported to AAB for Neutrophil % - 59.5 Results from instrument printout run on 09/20/2021 at 11:12:07 reported Neutrophil % - 59.1 No other instrument printouts were saved. 2021 3rd event sample "Vial 12" Results reported to AAB for Lymphocyte % - 28.2 Results from instrument

	printout run on 09/20/2021 at 11:12:07 reported Lymphocyte % - 26.2 No other instrument printouts were saved. 2021 3rd event sample "Vial 12" Results reported to AAB for Monocyte % - 5.8 Results from instrument printout run on 09/20/2021 at 11: 12:07 reported Monocyte % - 7.0 No other instrument printouts were saved. 2021 3rd event sample "Vial 12" Results reported to AAB for Eosinophil % - 6.2 Results from instrument printout run on 09/20/2021 at 11:12:07 reported Eosinophil % - 6.8 No other instrument printouts were saved. 2021 3rd event sample "Vial 12" Results reported to AAB for Basophil % - 0.3 Results from instrument printout run on 09/20 /2021 at 11:12:07 reported Basophil % - 0.9 No other instrument printouts were saved. 2021 3rd event sample "Vial 15" Results reported to AAB for Leukocytes - 3.5 Results from instrument printout run on 09/23/2021 at 14:37:32 reported WBC - 3.4 No other instrument printouts were saved. 2021 3rd event sample "Vial 15" Results reported to AAB for Neutrophil % - 53.8 Results from instrument printout run on 09 /23/2021 at 14:37:32 reported Neutrophil % - 51.8 No other instrument printouts were saved. 2021 3rd event sample "Vial 15" Results reported to AAB for Lymphocyte % - 34.4 Results from instrument printout run on 09/23/2021 at 14:37:32 reported Lymphocyte % - 38.0 No other instrument printouts were saved. 2021 3rd event sample "Vial 15" Results reported to AAB for Monocyte % - 3.9 Results from instrument printout run on 09/23/2021 at 14:37:32 reported Monocyte % - 1.9 No other instrument printouts were saved. 2021 3rd event sample "Vial 15" Results reported to AAB for Eosinophil % - 7.6 Results from instrument printout run on 09/23 /2021 at 14:37:32 reported Eosinophil % - 7.7 No other instrument printouts were saved. 2021 3rd event sample "Vial 15" Results reported to AAB for Basophil % - 0.3 Results from instrument printout run on 09/23/2021 at 14:37:32 reported Basophil % - 0.6 No other instrument printouts were saved. 2022 2nd event sample "Vial 6" to Vial 10" Results from instrument printout run on 05/20/2022 for Leukocytes, Erythrocytes, Hemoglobin, Hematocrit, and Platelet Count No other instrument printouts were saved. Results for Neutrophil %, Lymphocyte %, Monocyte %, Eosinophil %, and Basophil % were hand written on the instrument printout dated 05/20/2022. On 02/01 /2023 at 11:00 AM, Testing Personnel A stated that they may have rerun some samples and then threw away the printouts.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of American Association of Bioanalysts (AAB) proficiency testing (PT) records and interview, the previous Laboratory Director or the designee failed to document the review and evaluation of proficiency testing (PT) results for one (2022 1st event) of six (2021 1st, 2nd, 3rd & 2022 1st, 2nd, 3rd events) PT events. Findings included: Review of the AAB Proficiency Testing Performance Evaluation" revealed that the performance evaluation is grouped into two categories, Chemistry and Non-Chemistry. Chemistry includes the PT for Basic Chemistry, Cardiac Markers / Isoenzymes, Clinical Microscopy, Comprehensive Chemistry, Fertility - Endocrinology, Glycohemoglobin, High Sensitivity C-Reactive Protein, Immunochemistry, Iron Binding, Pregnancy, Therapeutic Drugs, Tumor Markers, Urinalysis, and Urine Drug Screening. Non-Chemistry includes the PT for Antinuclear Antibody, Antistreptolysin O, Blood Cell Identification, Chlamydia-GS-Strep Group B Antigen Screen, C (Clostridium) Difficile, Coagulation, C-Reactive

	Protein, Erythrocyte Sedimentation Rate, Helicobacter Pylori, Hematology with Diff C, Hepatitis Markers, Rubella, and Syphilis Serology. Review of the performance reviews showed there was no signature indicating the PT results were reviewed. On 02 /01/2023 at 10:05 AM, the Previous Laboratory Director (prior to 01/02/2023) acknowledged the performance reviews were not signed.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory test menu and proficiency testing (PT) records, and interview, the laboratory failed to verify the accuracy (PT) of ten analytes at least twice annually in 2021 and 2022, and two analytes at least twice annually in 2021. Findings included: 1. Review of the test menu provided with Clinical Laboratory Improvement Amendment (CLIA) Application for Certification indicated American Association of Bioanalysts (AAB) was the PT provider for the following analytes: Homocysteine, Low-Density Lipoprotein (LDL), Microalbumin, Prolactin, Sickle Cell, Testosterone, Total Iron Binding Capacity (TIBC), and Treponema Pallidium Particle Agglutination (T Pallidium-PA). Review of the PT records from AAB showed that there was no proficiency performed on Homocysteine, LDL, Microalbumin, Prolactin, Sickle Cell, Testosterone, TIBC, and T Pallidium PA in 2021 and 2022. Review of the test menu indicated PT was to be performed using the PT provider College of American Pathologists (CAP) for Haptoglobin. Review of the PT records from CAP showed that there was no proficiency performed on Haptoglobin in 2021 and 2022. Review of test menu indicated the PT for Lupus Erythematosus (LE) Latex was to be performed "In House." No documentation of "In House" testing for LE Latex was available for review. On 02/01/2023 at 4:25 PM, Testing Personnel A stated they did not do PT on the above mentioned analytes. 2. Review of the test menu indicated PT was to be performed using the PT AAB for Prostate Specific Antibody (PSA) and Vitamin B12. Review of the PT records from AAB showed that there was no proficiency performed on PSA) and Vitamin B12 in 2021. On 04/12/2023 at 6:30 PM, Testing Personnel A stated she was unable to locate the PT for PSA and Vitamin B12 for 2021.
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 observation, review of the procedure manual and test results, and interview, the laboratory failed to follow their written policy for specimen integrity for seven patient (patient #1-7 from 01/30/2023) samples observed on 01/30/2023. Findings

	included: On 01/30/23 at 10:30 AM during a tour of the laboratory seven patient specimens were found with only one patient identifier on the tubes. Review of the procedure titled "Specimen Integrity Qualification for Processing noted "Specimen container is clearly labeled with at least two patient identifiers." Review of patient test report showed that all seven patients samples were run and reported out. According to the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification signed and dated by the Laboratory Director on 01/30/2023, the laboratory had an estimated annual test volume of 193,513 tests per year. On 01/30 /2023 at 11:00 AM, Testing Personnel A acknowledged the specimens only had the patients name on the tubes.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on record review and staff interview, the laboratory did not meet the condition for Analytic Systems. Findings included: -Failure to evaluate if the IMMULITE 2000 XPi meet the performance specifications as per manufacturer instructions before patient testing. Refer to D5421.
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 interview, the laboratory failed to follow the procedure manual for the setup of the new International Sensitivity Index (ISI) value on the ACL

	Elite pro, since 03/21/2021. Findings include: -Review of the procedure manual revealed that the policy "INR Calculation ACL-Elite Pro" indicated the steps for the new ISI value to be added to the instrument to ensure appropriate International Normalized Ratio (INR) values results. -Review of "Daily Coagulation Quality Control Log" for years 2021 and 2022 revealed that the laboratory had new ISI values on April of 2021, May of 2021, June of 2021, August of 2021, August of 2022 and December of 2022. -Review of patient's final reports and instrument print outs for five patients tested in May 2021 revealed the following discrepancies between the instrument value and the reported value for the INR ratio: Patient#1: Tested on 05/25 /2021 with INR ratio in the instrument of 0.883, reported value was 0.91. Patient #2: Tested on 05/26/2021 with INR ratio in the instrument of 0.902, reported value was 0.93. Patient #3: Tested on 05/26/2021 with INR ratio in the instrument of 1.034, reported value was 1.06. Patient #4: Tested on 05/26/2021 with INR ratio in the instrument of 0.837, reported value was 0.86. Patient #5: Tested on 05/28/2023 with INR ratio in the instrument of 2.546, reported value was 2.62. -The laboratory failed to have documentation when the new ISI value was adjusted in the Laboratory Information System (LIS), and it was not possible to track when those changes were done. During an interview on 02/03/2023 at 02:00 PM, the laboratory owner confirmed that the laboratory failed to set up the new ISI value in the ACL Elite pro, she explained that because the instrument was not connected to the LIS, they have to manually enter the instruments results, so they added the new ISI value directly in the LIS and confirmed that the laboratory had no documentation when they performed the changes of the ISI value in the LIS.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on review of the instrument training manual and maintenance records, and interview, the laboratory failed to change the ISE (Ion-selective electrode) Reference Solution every 90 days on the Beckman Coulter AU680 Chemistry analyzer (annual test volume of 84,845) from 08/18/2021 to 02/03/2023. Findings included: The Beckman Coulter AU680 Chemistry analyzer uses three ISE reagents: ISE Buffer Solution, ISE Mid Standard Solution and the ISE Reference Solution. The "AU680 Chemistry Analyzer in-Lab Training Manual" noted "All three ISE Reagents have a 90-day onboard stability that needs to be tracked by the operator." Review of the Maintenance Schedule for the AU680 chemistry analyzer showed that the ISE Reference Solution was changed on 08/18/2021, 01/20/2022, 07/22/2022, and 01/12 /2023. There are 154 days between 08/18/2021 and 01/20/2022, 183 days between 01 /20/2022 and 07/22/2022, and 173 days between 07/22/2022, and 01/12/2023. On 02 /01/2023 at 3:00 PM, Testing Personnel A stated they were not changing the ISE Reference Solution as frequently they should.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it

	can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on lack of records and interview the laboratory failed to ensure the IMMULITE 2000 XPi analyzer met the manufacturer specifications before the starting of patient testing since 05/19/2022. Findings included: -Review of laboratory records revealed that the laboratory started testing patients with the IMMULITE 2000 XPi on 05/19/2022. -The laboratory had no records to document that performed an instrument verification before patient testing. The laboratory performed the following tests from 05/19/2022 to 02/03/2023: Vitamin B12: 590; Cortisol: 18; Estradiol: 92; Ferritin: 267; Folate (Folic Acid): 372; Follicle Stimulating Hormone: 47, Luteinizing Hormone: 16, Progesterone 41, Prolactin: 56, Prostate specific antigen: 909, Triiodothyronine (T3) T3-Total 165, to estimate the Thyroxine Binding Globulin (T3-Uptake): 36, Thyroxine (T4) free 399, T4 Total 299, testosterone Total 130, Thyroid Stimulating Hormone (TSH): TSH3-Ultra 2,128. During an Interview on 02/03/2023 at 02:30 PM, Testing Personnel A confirmed that the laboratory failed to do an instrument verification before patient testing for the IMMULITE 2000 XPi.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on IMMULITE 2000 XPi Immunoassay System maintenance records review and testing personnel (TP) A interview, the laboratory failed to follow manufacturer instructions to verify the calibrator adjustment with the required frequency since 05/17/2022 for the following analytes: Vitamin B12, Cortisol, Estradiol, Ferritin, Folate (Folic Acid), Follicle Stimulating Hormone (FSH), Luteinizing Hormone (LH), Progesterone, Prolactin, Prostate Specific Antigen (PSA), Triiodothyronine (T3) T3-Total, to estimate the Thyroxine Binding Globulin (T3-Uptake), Thyroxine (T4) Free, T4, Testosterone Total, Thyroid Stimulating Hormone (TSH): TSH3-Ultra. Findings included: -Review of IMMULITE 2000 XPi "Operator's Guide on section: Adjusting the System on Readjustment" it states that "Every assay must be periodically readjusted, as indicated in the kit's package insert, to correct for the reagent's normal loss of activity." Review of the IMMULITE 2000 XPi overview revealed that it stated that the "Reagent Barcode reader allows the system to identify lot number, and determine when calibrator adjustment needed, and the tests remaining in the reagent wedge." -Review of kit's packaging insert revealed the following requirements: Every week: Testosterone. Every two weeks: Vitamin B12, Progesterone, Free-PSA, T3-Total and T4 Free, T4. Every four weeks: Folate, Ferritin, T3-Uptake, PSA LH, Prolactin, FSH, TSH3-Tltra Review of Adjustment log records and instrument printouts since 05/19/2022 revealed the following: -The laboratory performed a calibration adjustment for: Vitamin B12, Cortisol, Estradiol, Ferritin, Folate, FSH,

	LH, Progesterone, Prolactin, PSA, T3-Total, T3-Uptake, T4 Free, T4, Testosterone Total, TSH3-Ultra analytes on 05/19/2022. -No records of Adjustment for: Vitamin B12, Cortisol, Estradiol, Ferritin, Folate, FSH, LH, Progesterone, Prolactin, PSA, T3-Total, T3-Uptake, T4 Free, T4, Testosterone Total, TSH3-Ultra found for June 2022. -No records of adjustment for Testosterone in July and October of 2022. -Review of instrument print out of proficiency testing samples tested in July revealed that the instrument flagged the PSA, T4 and T4Free tests as "Not Adjusted". -Review of instrument print out for controls revealed the following flags for the Kits: 09/06/2022: Not adjusted: T4 Free, T3-Uptake, T4. 09/27/2022: Not adjusted: T4 Free, Cortisol, Ferritin, T4, T3-Uptake, LH, TSH3-Ultra. 02/02/2023: Not adjusted: Testosterone, TSH3-Ultra. -Review of Testosterone Adjustment records revealed the following dates 08/05/2022, 09/14/2022, 11/17/2022, 11/23/2022, 12/19/2022. -No records of adjustment done on January 2023 for all analytes. -Review of Patients reported for the analytes Vitamin B12, Cortisol, Estradiol, Ferritin, Folate, FSH, LH, Progesterone, Prolactin, PSA, T3-Total, T3-Uptake, T4 Free, T4, Testosterone Total, TSH3-Ultra revealed that the laboratory performed tests in year 2023 in May, June, July, August, September, October, November, December, and in year 2023 in January and February. The total number of tests performed with the IMMULITE 2000 XPi from 05/19/2022 to 02/03/2023 were 5565. During an interview on 02/03/2023 at 3:00 PM, TP A confirmed that the laboratory failed to follow the manufacturer instruction for the calibration adjustment for the period of reference.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory's Quality Assessment (QA) failed to identify and correct the deficiency that the laboratory failed to verify the IMMULITE 2000 XPI analyzer prior to patient testing from 05/19/2022 to present. The QA failed to identify that the laboratory was not following manufacturer instructions for the calibrator adjustment for IMMULITE 2000 XPi. Findings included: -The QA failed to identify and correct that no verification of the IMMULITE 2000 XPi analyzer verification was done before patient testing. Refer D5421. -The QA failed to detect and correct the laboratory failed to follow the manufacturer instructions for the calibrator adjustment of the IMMULITE 2000 Xpi. Refer to D5429. During an interview on 02/03/2023 at 4:30 PM, the Lead Technologist confirmed that the QA failed to correct the deficiencies listed above.
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 revealed that the laboratory director (LD) from 01/2023 to present and the previous LD from 2021 to 2022 failed to effectively oversee the laboratory. Findings included: The previous LD failed to ensure the laboratory was enrolled in proficiency testing (PT) for 2021 and 2022. Refer to D6088. The previous LD failed to ensure the proficiency testing samples were tested as required under subpart H for 2021 and 2022. Refer to D6089. The previous LD failed to ensure PT results were reviewed for one (2022 1st event) of six (2021 1st, 2nd, 3rd & 2022 1st, 2nd, 3rd events) PT events. Refer to D6091. The previous LD failed to ensure that the laboratory verified that the IMMULITE 2000 XPi analyzer met the manufacturer specifications before patient testing on 05/19/2022 and the current LD failed to ensure the laboratory corrected the cited deficiency from 01 /2023. Refer to D6082 and D6094.
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: Based on record review and interview, the previous Laboratory Director failed to ensure the laboratory verified that the IMMULITE 2000 XPi analyzer met the manufacturer specifications before patient testing on 05/19/2022. Refer to D5421.
D6088	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4) The laboratory director must ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on review of the test menu and proficiency testing (PT) record, the previous Laboratory Director failed to ensure that the laboratory was enrolled in PT for 2021 and 2022 Findings included: The previous Laboratory Director failed to ensure the laboratory was enrolled PT from an approved PT program for three analytes in 2021 and 2022. Refer to D2000.
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and interviews, the previous Laboratory Director failed to ensure the proficiency testing samples were tested as required under subpart H for 2021 and 2022. Findings included: The laboratory failed to treat PT samples in the same manner as patients for five (2021 1st, 2nd, 3rd and

	2022 1st, 2nd) of six (2021 1st, 2nd, 3rd and 2022 1st, 2nd, 3rd) testing events reviewed in the specialty of Hematology. Refer to D2006. The laboratory failed to have all testing personnel rotate through testing of PT samples for PT in the specialties of Diagnostic Immunology, Chemistry and Hematology for six of six (2021 1st, 2nd, 3rd, and 2022 1st, 2nd, 3rd) events. Refer to D2007. The laboratory failed to have the Laboratory Director and the Testing Personnel sign the attestation form for PT in the specialties of Chemistry, Diagnostic Immunology Hematology, and Microbiology for 6 of 6 (2021 1st, 2nd, 3rd, 2022 1st, 2nd, 3rd) testing events. Refer to D2009. The laboratory failed retain the Hematology instrument printout when they reran PT samples for two (2021 3rd, 2022 2nd) of six (2021 1st, 2nd, 3rd, and 2022 1st, 2nd, 3rd) events. Refer to D2015.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and interview, the previous Laboratory Director failed to ensure PT results were reviewed for one (2022 1st event) of six (2021 1st, 2nd, 3rd & 2022 1st, 2nd, 3rd events) PT events. Findings included: The previous Laboratory Director or the designee failed to document the review and evaluation of proficiency testing (PT) results for one (2022 1st event) of six (2021 1st, 2nd, 3rd & 2022 1st, 2nd, 3rd events) PT events. Refer to D5211.
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: Based on record review and interview, the Laboratory Director (LD) from 01/2023 to present and previous LD (2021 to 2022) failed to ensure the laboratory Quality Assessment (QA) identified and corrected the failure of the laboratory performing tests with the IMULITE 2000 XPi analyzer without verifying that the analyzer met the manufacturer requirements. Findings included: -The QA failed to correct that the laboratory failed to verify the IMMULITE 200 XPi met the manufacturer specifications. Refer to D5791. During an interview on 02/03/2023 at 02:00 PM, the current LD confirmed that he failed to ensure the laboratory QA identified and corrected the deficiency listed above.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.

	This STANDARD is not met as evidenced by: Based on review of competency records and interview, the laboratory failed to retain the documentation of the initial training for one (C) of 5 (A - E) Testing Personnel (TP). Findings included: Review of the competency records revealed there was only a six month competency evaluation dated 12/22/2022 for TP-C. On 02/02/2023 at 4:00 PM, Testing Personnel A confirmed that TP-C's hired date was 06/01/2023, and that she did not know where TP-C's initial training competency was located.