Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0893124	05/19/2022
Name of Provider or Supplier	**Street Address, City, State**	
First Care Medical Clinic	404 South Sutherland Avenue, Monroe, NC	

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 initial certification survey was conducted May 18-19, 2022. Based on the survey findings, Immediate Jeopardy was identified and the laboratory was notified May 19, 2022 at approximately 4:10 p.m. The laboratory failed to identify and correct problems in the specialty of hematology and the subspecialties of bacteriology, mycology, parasitology, routine chemistry, and endocrinology. The laboratory performs approximately 203,980 tests per year.
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on review of manufacturer's IFU (Instructions for Use), review of personnel records, review of the FDA (Food and Drug Administration) website, review of the laboratory's policies and procedures, and interview with TP (testing personnel) #2 on 5 /18/22, the laboratory failed to follow manufacturer's instructions for performing the Sienna-Clarity COVID-19 Antigen Rapid Test Cassette. Findings: 1. The laboratory failed to follow manufacturer's IFU to ensure 5 of 5 TP were trained prior to testing patients for SARS-CoV-2 using the Sienna-Clarity COVID-19 Antigen Rapid Test Cassette test kit. Manufacturer's IFU printed from the FDA website state "INTENDED USE ... The Sienna-Clarity COVID-19 Antigen Rapid Test Cassette is intended for use by trained clinical laboratory personnel and individuals trained in point of care. The Sienna-Clarity COVID-19 Antigen Rapid Test Cassette is only for use under the Food and Drug Administration's Emergency Use Authorization. ... CONDITIONS OF AUTHORIZATION FOR THE LABORATORY ... F. All operators using your product must be appropriately trained in performing and interpreting the results of your product. Use appropriate personal protective

	equipment when handling this kit, and use your product in accordance with the labeling. ..." During interview at approximately 12:10 p.m., TP #2 stated that in addition to the two laboratory personnel (TP #1 and TP #2), 3 medical assistants also perform COVID testing. He confirmed there were no training records available for any of the 5 testing personnel who perform COVID testing. 2. The laboratory failed to follow manufacturer's IFU to include Fact Sheets with patient test results. Manufacturer's IFU printed from the FDA website state "... CONDITIONS OF AUTHORIZATION FOR THE LABORATORY ... A. Authorized laboratories using your product must include, with test reports, all Fact Sheets. ..." Review of the FDA website revealed a "FACT SHEET FOR PATIENTS" and a "FACT SHEET FOR HEALTHCARE PROVIDERS". During interview at approximately 12:30 p.m., TP #2 confirmed that Fact Sheets were not given to patients with their COVID test results. 3. The laboratory failed to follow manufacturer's IFU to establish a process for reporting patient test results to state and/or local public health authorities. Manufacturer's IFU printed from the FDA website state "... D. Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate. ..." Review of the laboratory's "COVID-19 Antigen Rapid Test Policy" revealed it did not include instructions for reporting patient SARS-CoV-2 antigen test results to state and/or local public health authorities. During interview at approximately 12:30 p.m., TP #2 stated positive results are faxed to the health department. He verified the laboratory did not have a written procedure for reporting patient SARS-CoV-2 antigen test results to state and/or local public health authorities.
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 CMS (Centers for Medicare and Medicaid Services) Casper report 155D, review of 2019, 2020, 2021, and 2022 API (American Proficiency Institute) PT (proficiency testing) records, and interview with TP #2 on 5/18/22, the laboratory failed to enroll in an approved PT program for the BD (Becton Dickinson) Affirm VPIII testing in the subspecialty of Bacteriology. Findings: The laboratory performs testing for Gardnerella, Trichomonas, and Candida using the BD Affirm VPIII test. Review of the CMS Casper report 155D and 2019, 2020, 2021, and 2022 API proficiency testing records revealed the laboratory had not enrolled in PT for the regulated subspecialty of Bacteriology for 2019, 2020, 2021, and 2022. During interview at approximately 10:30 a.m on 5/18/22, TP #2 confirmed the laboratory was not enrolled in PT for the BD Affirm testing.
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 the laboratory's policies, review of 2019, 2020, 2021, and 2022 API PT records, and absence of documentation 5/18/22, the laboratory failed to maintain all PT records and failed to ensure the LD (laboratory director) and TP signed the attestation statements for testing events in 2019, 2020, and 2021. Findings: The laboratory's "Proficiency Testing & Split Testing Policy" states, "...Proficiency Testing Guidelines....The lab director or designee and testing personnel should sign the attestation page prior to submitting results... Primary records related to PT and alternate testing should be retained for two years unless longer retention is required for specific analytes...." Review of 2019, 2020, 2021, and 2022 API PT records revealed: 1. The laboratory failed to maintain the PT evaluation reports for 2019 3rd Hematology testing event and 2020 Chemistry Core and Hematology 2nd testing events. Review of records revealed the laboratory had only the API performance summary on file but no documentation of the evaluation reports for all analytes tested. 2. The laboratory failed to ensure the LD and/or TP signed the attestation for 2019 Chemistry Miscellaneous 2nd testing event, 2019 Hematology 3rd testing event, 2020 Chemistry Core and Hematology 3rd testing events, 2021 Hematology 1st testing event, and 2021 Chemistry Core 2nd testing event.
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on random review of SARS-CoV-2 patient logs and interview with TP (testing personnel) #2 on 5/18/22, the laboratory failed to report all positive and negative SARS-CoV-2 test results to state or local public health authorities. The laboratory performs SARS-CoV-2 antigen testing using the Sienna-Clarity COVID-19 Antigen Rapid Test Cassette. Random review of SARS-CoV-2 patient logs revealed: 1. On 12 /1/21, the laboratory tested 12 patients. The 2 patients that tested positive had "Faxed" written beside their names on the log. There was no documentation that public health

	authorities were notified of the 10 negative results. 2. On 12/30/21, the laboratory tested 75 patients. 25 patients tested positive and 50 patients tested negative. There was no documentation that public health authorities were notified of any of the results. 3. On 1/22/22, the laboratory tested 47 patients. 9 patients tested positive and 38 patients tested negative. There was no documentation that public health authorities were notified of any of the results. 4. On 2/1/22, the laboratory tested 24 patients. 2 patients tested positive and 22 patients tested negative. There was no documentation that public health authorities were notified of any of the results. 5. On 5/4/22, the laboratory tested 5 patients. The 2 patients that tested positive had "Faxed Results" written beside their names on the log. There was no documentation that public health authorities were notified of the 3 negative results. Review of SARS-CoV-2 patient logs revealed the following statement printed at the bottom of each log sheet with a fax number: "Fax positive Covid to Health Department". Random review of SARS-CoV-2 patient logs also revealed multiple logs that did not include a test date and multiple logs which included only the first names of patients with no other identifier. During interview 5/18/22 at approximately 2:15 p.m., TP #2 stated that they fax positive results to the health department. He stated that TP #1 usually documents on the patient log if she faxes the result to the health department, but nobody else documents faxing results. He stated they do not keep fax confirmations or any other documentation to verify that the results were transmitted. He confirmed it was difficult to determine which patients were tested on which dates based on the documentation available.
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's policies, review of 2019, 2020, 2021, and 2022 API PT records and alternate PT records 5/18/22, the laboratory failed to verify accuracy of testing twice a year for the Qualitative urine drug screen in 2021 and for HA1c (glycosylated hemoglobin) in 2019, 2020, 2021, and 2022. Findings: The laboratory's "Alternate Proficiency/ Split Testing Program" policy states, "Alternate Proficiency Testing/Split Testing is required if the lab is not participating in CAP/API or other participating PT agency....This Alternate PT or Split testing should be performed at least twice (2) a year or Semi-annually..." Review of the 2019, 2020, 2021, and 2022 API PT records revealed the laboratory performed API Chemistry Miscellaneous 1st event in 2021 for the Qualitative Urine drug screen. There was no documentation that the laboratory participated or verified accuracy of the Qualitative urine drug screen for the 2nd event of 2021. Review of API PT records and alternate PT records revealed the laboratory had not verified accuracy for the HA1c test in 2019, 2020, 2021, and 2022.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by:

	Based on review of the laboratory's policies, review of the 2019, 2020, 2021, and 2022 API PT, and absence of documentation 5/18/22, the laboratory failed to document evaluation and corrective action of all PT results received. Findings: The laboratory's "Proficiency Testing & Split Testing Policy" states, "...Survey performance resulting in a score of less than 100% will require further investigation and corrective action....Unsatisfactory performance for 1 or more analytes on an event will receive a PT Exception Summary(PTES) report. Laboratory must: Investigate problem. Determine Cause. Implement Corrective action...." Review of 2019, 2020, 2021, and 2022 API PT records revealed the laboratory failed to document evaluation and corrective action for all unsatisfactory PT results. Examples: 1. 2019 3rd Chemistry Core event: 60% score for Total Cholesterol and 20% score for LDL (low-density lipoprotein) Cholesterol with no corrective action documented; 2. 2020 2nd Chemistry Core event: 80% score LDL Cholesterol with no corrective action documented; 3. 2020 2nd Hematology event: 40% score for MPV (mean platelet volume) with no corrective action documented; 4. 2020 2nd Chemistry Miscellaneous event: 67% score for Amphetamines and Methadone. A "notation of corrective action" signed by the current lab director with no date, was on file that listed the failure, but no specific investigation or corrective action was given for the cause of the failure; 5. 2020 3rd Chemistry Core event: 50% score for PSA (prostate specific antigen) and 80% score for Total Protein. A "notation of corrective action" signed by the current lab director with no date, was on file that listed the failure for the PSA, but no specific investigation or corrective action was given for the cause of the failure. No corrective action documented for the Total Protein. 6. 2020 3rd Hematology event: 80% score for HCT (hematocrit), MCV (mean corpuscular volume), and RDW (red cell distribution width) with no corrective action; 7. 2021 1st Chemistry Core event: 80% score for HDL (high-density lipoprotein) with no corrective action; 8. 2021 1st Hematology event: 20% score for RBC (red blood cell), MCH (mean corpuscular hemoglobin), MCV, RDW, and 80% score for HCT and Platelet. A "notation of corrective action" signed by the current lab director with no date, was on file that listed the failures/unacceptable results, but no specific investigation or corrective action was given for the cause of the failures/unacceptable results.
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 review of laboratory records 5/18/22 and 5/19/22, the laboratory failed to monitor and evaluate the ongoing and overall quality of the analytic systems to identify and correct problems and prevent their recurrence. Findings: 1. The laboratory failed to have a complete procedure manual available for all testing performed (see D5403). 2. The laboratory failed to follow manufacturer's instructions for performance of the Affirm VPIII test, and failed to follow manufacturer's instructions for specimen acceptability of chemistry testing performed (see D5411). 3. The laboratory failed to define acceptable ranges for room and freezer temperatures that were consistent with the manufacturer's instructions and failed to monitor and

	document temperatures each day of patient testing (see D5413). 4. The laboratory failed to discard control materials and reagents that had exceeded their expiration dates (see D5417). 5. The laboratory failed to verify the performance of the LIS (laboratory information system) and EMR (electronic medical record) when testing was implemented on the Access 2 and AU480 chemistry analyzers (see D5421). 6. The laboratory failed to perform and document maintenance as required for the Cell-Dyn 1800 and AU480 (see D5429). 7. The laboratory failed to perform and document calibrations at the frequency specified by the manufacturer for the Access 2 (see D5437). 8. The laboratory failed to perform and document calibration verification at least twice a year for analytes tested on the AU480 (see D5439). 9. The laboratory failed to obtain at least two levels of acceptable QC each day of patient testing for the Cell-Dyn 1800 hematology analyzer and the AU480 chemistry analyzer (see D5447). 10. The laboratory failed to perform and document positive and negative external controls each day of testing or establish an IQCP (Individualized Quality Control Plan) and failed to document internal positive and negative internal controls with each patient test for the Affirm VPIII (see D5449). 11. The laboratory failed to verify QC ranges when new lot numbers of QC were put into use for the Access 2 chemistry analyzer (see D5469).
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 review of laboratory procedure manual, surveyor observation and interview with TP #2 on 5/18/22 and 5/19/22, the procedure manual was not complete and current for the testing performed. Findings: 1. Review of procedure manual revealed the procedures for QC on the Access 2 chemistry analyzer failed to include the type and levels of QC used for each analyte tested. Review of procedure manual revealed manufacturer's IFU for each analyte tested on the Access 2 chemistry analyzer. The IFU's included the same information for QC and each failed to state the type (manufacturer) and levels of QC used by the laboratory for each analyte. For example, review of "Free T4" (FT4) manufacturer's IFU revealed "quality control materials should be included in each 24 hour time period, include commercially available quality control materials that cover at least two levels of analyte." and under

"MATERIALS NEEDED BUT NOT SUPPLIED...2. Quality Control (QC) materials: commercial control material." Review of policy "Quality Assurance and Management Policy" revealed "Quality Control...Procedures for internal quality control should be developed by the section manager/supervisor...Internal QC procedures should be appropriate for the ...testing performed, and instruments utilized....Internal QC procedures should meet regulatory requirements...". The policy failed to state the type (manufacturer) and levels of QC used by the laboratory for each analyte. 2. Review of procedure manual revealed the procedures for calibration on the Access 2 chemistry analyzer failed to include the criteria for acceptance and the actions to take if calibration fails. Review of procedure manual revealed manufacturer's IFU for each analyte tested on the Access 2 chemistry analyzer. The IFU's included the same information for calibration and each failed to state the criteria used to determine acceptable calibration results and also failed to include the actions to take if calibration fails. For example, review of "Prostate-Specific Antigen" manufacturer's instructions for use revealed "CALIBRATION...CALIBRATION INFORMATION... Refer to the appropriate system manuals and/or Help system for information on... reviewing calibration data." Review of procedure manual for "appropriate system manuals and/or Help system" revealed no documentation of "system manuals and/or Help system". 3. Review of procedure manual revealed the manual included procedures for the Dimension chemistry analyzer. During laboratory tour, 5/18/22, at approximately 9:45 a.m. surveyors did not observe a Dimension chemistry analyzer in the laboratory. Interview with TP #2, 5/18/22, at approximately 10:35 a.m. confirmed the laboratory does not have a Dimension chemistry analyzer. He stated it was replaced in January of 2020 with the Access 2 and AU480 analyzers. 4. Review of the procedure manual revealed procedures for the AU480 Chemistry analyzer failed to include the manufacturer's IFU for all analytes tested on the AU480, failed to include the type and levels of QC and calibration materials tested on the AU480, failed to include the frequency for QC and calibration, and failed to include the criteria for acceptance and the actions to take if QC or calibration fails. a. Review of the laboratory's procedures revealed the manufacturer's IFU included only the Qualitative urine drug screens tested on the AU480. The laboratory failed to include the IFU's for all other analytes tested on the AU480. At approximately 3 p.m. on 5/19/22, TP #2 stated the manufacturer's IFU's for the chemistry analytes are located in the online Beckman Coulter AU480 User's guide. He was able to print an example of the TBIL (total bilirubin) and Glucose instructions for use as examples. b. Review of the procedure manual revealed a "Beckman AU480 analyzer maintenance policy and procedure" and Beckman Olympus AU Chemistry Analyzer Operations Policy & Procedure". The procedures reviewed did not include the type and levels of QC and calibration materials for the AU480, did not include the frequency for QC and Calibration, and did not include the criteria for acceptance or steps to take if QC or calibration fails. Review of the IFU for TBIL printed during the survey revealed for QC, "...at least two levels of an appropriate quality control material should be tested a minimum of once a day...". The IFU failed to include the control name, sample type, or storage information for the QC material. The TBIL IFU revealed a calibration frequency and the use of the Chemistry Calibrator. Online review of the AU480 user's guide by the surveyor revealed similar QC and calibration information for other analytes tested, but the information was not available at time of survey. 5. Review of the procedure manual revealed the laboratory has two procedures for the Hematology Cell-Dyn analyzer and each procedure has different reference ranges: The "Cell Dyn 1800 Hematology Analyzer" has reference ranges listed for an adult female as: WBC (white blood cell): 4.5-11.0x10^3/UL(microliter) Lymph%(lymphocyte percent): 25-40% Mono(Monocytes) %: 4-12% Gran(Granulocytes) %: 50-73% RBC(Red Blood cell): 4.0-5.2 x10^6/UL Hgb(hemoglobin): 12.0-15.0g/dL(grams/deciliter) HCT

	(hematocrit): 35.8-47.9% MCV(Mean corpuscular volume): 82-98fl(femtoliter) MCH (Mean corpuscular hemoglobin): 26-34pg(picogram) MCHC(Mean corpuscular hemoglobin concentration): 31-37g/dL RDW(red cell distribution width): 11.7-16.5% PLT(platelets): 150-400 x10^3/UL MPV(mean platelet volume): 5.9-9.4fl The "Hematology Policy & Procedure Complete Blood Count Test: Results & Normal Values" has different reference ranges listed for a female: WBC 4,000-11,000cells/cu. mm(cubic millimeter) RBC 3.9-5.6 x10^6/cu.mm Hgb 11.5-16.5g% HCT 30-40% MCV 76-96um3(micrometer cubed) MCH 27-32pg MCHC 30-35% PLT 15,000-450,000cu.mm This deficiency was cited on the previous survey 7/2/19.
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 review of manufacturers' instructions, review of the laboratory's policies and procedures, review of BD Affirm VPIII patient and QC logs, observation, review of temperature logs, review of 2022 Access 2 and AU480 maintenance logs, and interview with TP #2 on 5/18/22, the laboratory failed to follow manufacturers' instructions for performance of the BD Affirm VPIII test, the testing performed on the Access 2 analyzer and the testing performed on the AU480 analyzer. Findings: Affirm VPIII 1. The laboratory failed to document testing each new lot number of test kits for adequate sample lysis and release of target nucleic acid. Manufacturer's instructions for the The BD Affirm VPIII Microbial Identification Test state on page 4 "... Each reagent lot must be tested for adequate sample lysis and release of target nucleic acid using a swab streak of fresh iundicator culture (18-24 h growth) or commercially prepared swab of Candida albicans ... To further verify test performance, quality control testing with C. albicans (ATCC 10231), T. vaginalis (ATCC 30001) and G. vaginalis (ATCC 14018) may be conducted using fresh indicator cultures (18-24 h growth) or commercially prepared swabs. The laboratory's "BD Affirm" procedure includes the QC information included in the manufacturer's instructions and states on page 4 "... External 1. Each reagent lot and shipment must be tested for adequate sample lysis and release of target nucleic acid using a commercially prepared swabs. 2. A clean, sterile swab may be used for the negative external control. ...". Review of Affirm VPIII QC logs revealed the laboratory tested a trivalent control for 4 lot numbers of kits from 8/6/19 - 4/16/21. Review of Affirm VPIII patient logs revealed the only patient logs available were for patients tested 4/19/19 - 11/6/19, and patients tested 1/13/21 - 4/10/21. During a tour of the laboratory 5/18/22 at approximately 3:00 p.m., the surveyor observed the Affirm VPIII kit (lot #1321439, expiration date 10/12 /22) currently in use stored on a shelf in the laboratory. There was no documentation that the laboratory had tested the current lot for adequate sample lysis and release of target nucleic acid as specified by the manufacturer's instructions and the laboratory's procedure. During interview at approximately 4:00 p.m., TP #2 stated that they had not tested each new lot number for adequate sample lysis and release of target nucleic acid. He stated they did not know it was required. 2. The laboratory failed to perform and document positive and negative external controls each day of testing or establish an IQCP (Individualized Quality Control Plan) and failed to document positive and negative internal controls with each patient test from 4/11/21 to 5/19/22 (see D5449).

	3. The laboratory failed to document the temperature of the lysis block each day of testing from 11/7/19 to 1/12/21 and 5/9/21 to 5/19/22 to ensure the manufacturer's specified temperature of 85+/-5 degrees C (see D5413). 4. The laboratory failed to ensure a room temperature of 22-28 degrees C for performance of the test (see D5413). Access 2 and AU480 1. The laboratory failed to follow manufacturer's IFU's for specimen acceptability and reported patient test results on specimens that were unacceptable. Review of 2022 Access 2 and AU480 maintenance logs revealed no documentation of daily maintenance from 1/28/22 through 2/6/22, approximately 10 days, and 2/24/22 through 3/6/22, approximately 11 days. Interview with TP #2 on 5 /18/22 at approximately 2:00 p.m. confirmed daily maintenance for the chemistry analyzers was not performed from 1/28/22 through 2/6/22 and also 2/24/22 through 3 /6/22. He stated he was taking time off and all specimens for chemistry testing were spun down and held in the refrigerator at 2-8 degrees Celsius (C) until he returned and testing resumed. Review of manufacturer's IFU's revealed multiple analytes tested on the AU480 and Access 2 had specimen acceptability of less than 10 days when spun down and refrigerated. For example: a. VB12 - specimen stability of 24 hours at 2-8 degrees C. b. FT4 - specimen stability of 48 hours at 2-8 degrees C. c. VITD - specimen stability of 7 days at 2-8 degrees C. d. TSH - specimen stability of 7 days at 2-8 degrees C. e. Glucose (GLU) - specimen stability of 72 hours at 2-8 degrees C. f. Total Bilirubin (TBIL) - specimen stability of 3 days at 2-8 degrees C.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of manufacturer's IFU's, review of 2019, 2020, 2021, and 2022 temperature logs, observation, and review of Affirm VPIII patient logs 5/18/22 and 5 /19/22, the laboratory failed to define acceptable ranges for room and freezer temperatures that were consistent with the manufacturers' instructions and failed to monitor and document room, lysis block, and freezer temperatures each day of patient testing. Findings: A. Affirm VPIII The manufacturer's product insert for the BD Affirm VPIII Microbial Identification Test states on page 2 "... Warnings and Precautions ... With each test run, monitor the temperature of Lysis Block, 85+/- 5 degrees C (Celsius) and verify that the testing environment temperature is between 22 and 28 degrees C. ..." On page 3, it states "Storage of Reagents ... All reagents and PACs must be at 22 to 28 degrees C prior to use. ... PROCEDURE ... 1. Verify that the BD MicroProbe Lysis Block is at 85+/-5 degrees C, and that reagents are at 22-28 degrees C and well mixed. ..." Review of 2019, 2020, 2021, and 2022 temperature logs revealed: 1. The acceptable range for room temperature was listed on the temperature logs as 19-24 degrees C which was not consistent with the manufacturer's specified range of 22-28 degrees C for performance of the Affirm VPIII test. 2. Room temperature was outside the manufacturer's specified acceptable limits of 22-28 degrees C on multiple days. Examples: a. 18 of 18 days in June 2021 (1, 2, 3, 4, 7, 8, 9, 10, 12, 14, 15, 18, 21, 23, 26, 28, 29, 30). There were 7 other days in June 2021

	with no temperatures documented; b. 153 of 153 days from July 1 - December 31, 2021; c. 107 of 107 days from January 10 - May 18, 2022. There were no room temperatures documented 1/2/21 - 5/10/21 and 1/3/22 - 1/8/22. Review of Affirm VPIII patient logs revealed the log included a space to document room temperature and indicated the correct acceptable range (22-28 degrees C), but the laboratory failed to use the logs consistently to document patient testing. The only patient logs available were for patients tested 4/19/19 - 11/6/19, and patients tested 1/13/21 - 4/10 /21. On the patient log which included 17 patients tested 1/13/21 - 4/8/21, there was no room temperature documented. 3. The laboratory failed to document the lysis block temperature 11/7/19 - 1/12/21 and 5/9/21 - 5/19/22. B. BIO-RAD Liquichek Specialty Immunoassay Control Review of manufacturer's instructions for the BIO-RAD Liquichek Specialty Immunoassay Control Levels LTA, I, 2, and 3 revealed "... STORAGE AND STABILITY This product will be stable until the expiration date when stored unopened at -20 to -70 degrees C. For optimum performance, avoid storing this product in a frost-free freezer. ..." During a tour of the laboratory at approximately 9:40 a.m., surveyors observed BIO-RAD Liquichek Specialty Immunoassay Control material stored in the black freezer in the laboratory. Review of 2019, 2020, 2021, and 2022 temperature logs revealed the laboratory's acceptable range for the black freezer was listed as -20 to -25 degrees C. Review of the temperature logs revealed temperatures documented for the black freezer were frequently warmer than -20 degrees C. For example, temperatures were warmer than -20 degrees C on the following days: a. 2 of 22 days in May 2021 (22, 26); b. 13 of 26 days in December 2021 (6, 7, 8, 9, 13, 14, 21, 23, 24, 27, 29, 30, 31); c. 17 of 24 days in February 2022 (1, 2, 4, 7, 8, 9, 11, 14, 15, 16, 18, 19, 21, 23, 24, 25, 26); d. 22 of 25 days in April 2022 (1, 4, 5, 6, 7, 8, 11, 12, 13, 14, 15, 16, 18, 19, 20, 21, 22, 23, 25, 26, 28, 29). In addition, there were no freezer temperatures documented 11/19/19 - 12 /31/20.
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 random review of 2020, 2021, and 2022 Hematology QC records, review of the hematology manufacturer's QC package insert, surveyor observation, and interview with TP #2 on 5/18/22, the laboratory failed to discard control materials and reagents that had exceeded their expiration dates. Findings: 1. Random review of 2020, 2021, and 2022 Hematology QC records and the Streck Para 12 Extend control package insert revealed lot #01600422/01600423/01600424 expired on 12/14/20 and was in use for 12 days in December 2020(12/15, 12/16, 12/17, 12/18, 12/21, 12/22, 12 /23, 12/26, 12/28, 12/29, 12/30, 12/31). 2. During a tour of the laboratory at approximately 9:30-9:45 a.m., the surveyors observed the following expired reagents located in the Chemistry Refrigerator available for use: a. 1 open bottle of ISE Cleaning solution, lot # 863480, expiration date 11/2020; b. 1 full box (6 bottles) of Bicarbonate calibrator, lot # 2714, expiration date 3/14/22; c. 1 partial box(4 bottles) of Bicarbonate calibrator, lot #2715, expiration date 3/27/22; d. 1 open bottle of MAS Diabetes -liquid assayed Level 1 control, lot # DBCL21071A, expiration date 7/31/21; e. 1 open bottle of MAS Diabetes- liquid assayed Level 2 control, lot # DBCL21072A, expiration date 7/31/21. 3. During a tour of the laboratory at

	approximately 9:45 a.m., the surveyors observed the following expired reagents on a shelf in the laboratory available for use: a. 1 open bottle of Beckman Coulter ISE Low Urine Standard, lot #2674, expiration date 5/9/22; b. 1 open bottle of Beckman Coulter ISE High Urine Standard, lot #2674, expiration date 5/10/22; c. 1 open bottle of Beckman Coulter Bicarbonate Calibrator, lot #2715, expiration date 3/27/22. d. 1 open bottle of sodium hydroxide solution, W2 wash solution, lot #HC98779041, expiration date (minimum shelf life) 3/31/22. 4. During a tour of the laboratory at approximately 3:00 p.m., the surveyors observed the following expired supplies in the door of the black refrigerator available for use: a. 1 box of Validate HbA1c Calibration Verification Test Set Levels 1-5, lot #65AO282190, expiration date 1/25 /21; b. 1 partial box of extendSURE HbA1c Liquid Controls, lot #4188, expiration date 8/31/21; c. 1 partial box of extendSURE HbA1c Liquid Controls, lot #4204, expiration date 3/31/22. During interview at approximately 3:30 p.m., TP #2 stated he had never used the expired supplies found in the door of the black refrigerator. This deficiency was cited on the previous survey 7/2/19.
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 review of laboratory policy, review of laboratory verification of performance records and interview with TP #2 on 5/18/22, the laboratory failed to verify the performance of the laboratory information systems (LIS), Merge and eClinical, to ensure the correct transmission of test result data from the Access 2 analyzer since testing began in January of 2020 and from the AU480 analyzer since testing began in July of 2020. Findings: Review of laboratory policy "Data Transmission Verification Laboratory Information System" revealed "The release of results from clinical instruments via algorithms running in a laboratory information system...be accomplished within regulatory frameworks. There are a number of issues that need to be taken into account prior to implementing such a process. Capabilities of the instrumentation in terms of validity of results, error flags, data management, and transmission...". Review of laboratory verification of performance records revealed no documentation the laboratory verified the performance of the Merge and eClinical LIS prior to performing patient testing in January of 2020. Interview with TP #2 at approximately 10:35 a.m. confirmed the laboratory records failed to include documentation of a verification of performance of the LIS, Merge and eClinical. He stated he was not employed when the laboratory installed the Access 2 and AU480 analyzers and he could not locate any documentation the verification of performance of the LIS was performed prior to beginning patient testing.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory

	must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures, review of manufacturers' instructions, review of laboratory records, and interview with TP #2 on 5/19/22, the laboratory failed to perform and document maintenance on the Abbott Cell-Dyn 1800 Hematology analyzer and the AU480 Chemistry analyzer as required. Findings: Review of the laboratory's "General Maintenance Policy" revealed, "... all major or minor instrument and small devices are required to have maintenance performed in accordance with the manufacturer guidelines or Laboratory policies...Instrument maintenance logs are required to be completed in a timely fashion and filed for lab record in a combined binder or the individual instrument maintenance binder...". 1. The laboratory's Cell-Dyn 1800 Hematology policy and the Cell-Dyn 1800 System Operator's Manual revealed for Maintenance, "Daily. Start-up...Shutdown... Weekly. Open Sample Auto-Clean... Aspiration Probe Exterior Cleaning.. QC Review... Monthly. Lyse Inlet Tubing Rinse...Reagent Inlet Tubing Rinse...". Review of the Cell-Dyn 1800 records revealed the laboratory failed to perform and document maintenance for the following: Daily: a. May 2021- no startup/shutdown for 5/24, 5 /25, 5/26, 5/27; b. June 2021- no startup for 6/11; no startup/shutdown for 6/21, 6/22, 6 /23, 6/24, 6/25; c. November 2021- no shutdown for 11/26, 11/29, 11/30; e. December 2021- no shutdown for 12/1, 12/2, 12/3, 12/4, 12/6, 12/10, 12/15, 12/16, 12/17, 12/18, 12/27, 12/28, 12/29, 12/30, 12/31. Weekly: a. May 2021: weeks of 5/10, 5/17, 5/24; b. June 2021: weeks of 6/1, 6/7, 6/14, 6/21; c. July 2021: weeks of 7/5, 7/12, 7/19, 7/26; d. August 2021: weeks of 8/2, 8/9, 8/16, 8/23, 8/30; e. September 2021: weeks of 9/6, 9/13, 9/20, 9/27; f. October 2021: weeks of 10/4, 10/11, 10/18, 10/25; g. November 2021: weeks of 11/1, 11/8, 11/15, 11/22, 11/29; h. December 2021: weeks of 12/6, 12 /13, 12/20, 12/27; i. January 2022: weeks of 1/3, 1/17; j. February 2022: weeks of 2/1, 2/7. Monthly: a. No monthly maintenance from May 2021 to April 2022. 2. The online Beckman Coulter AU480 User's Guide revealed a Maintenance schedule list for Daily, Weekly, every other week, Monthly, Every other month, Quarterly, Every 6 months, and Every 2 years. For example: weekly, a W2(cleaning of the cuvettes) and a photocal is performed; Quarterly, the air filters are cleaned; every 6 months, the Na (sodium), Cl(chloride), and K(potassium) electrodes are replaced. Review of laboratory records revealed there was no maintenance for the AU480 from the time the laboratory began testing on the analyzer in July 2020 to November 2021, a period of approximately 16 months. At approximately 2:45 p.m., TP #2 stated that he could not find any maintenance documentation for the AU480 when he started in November 2021.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration

verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:
Based on review of manufacturer's instructions and review of 2020 and 2021 Access 2 calibration records 5/18/22, the laboratory failed to perform calibrations on the Access 2 chemistry analyzers at the frequency required by manufacturer. Findings: The laboratory began testing for Vitamin B12 (B12), 25-Hydroxy Vitamin D (VitD), Free Thyroxine (FT4), 3rd generation thyroid-stimulating hormone (TSH3), and Prostate-specific antigen (PSA) in January of 2020. 1. The laboratory failed to perform B12 calibrations at the frequency required by manufacturer. Findings: Review of manufacturer's instructions for B12 revealed on page 6, "CALIBRATION...calibration is required every 21 days.". Review of B12 calibration records revealed the following calibrations were not performed every 21 days as required. a. The first calibration performed after testing began in January of 2020 was on 3/30/20, greater than approximately 60 days after testing began. b. Lot #922969 calibrated on 4/14/21, expired on 5/5/21, no documentation of calibration until 6/18/21, approximately 35 days after calibration expired. c. Lot #923034 calibrated on 7/14/21, expired on 8/4 /21, no documentation of calibration until 11/29/21, approximately 117 days after calibration expired. 2. The laboratory failed to perform VitD calibrations at the frequency required by manufacturer. Findings: Review of manufacturer's instructions for VitD revealed on page 8, "CALIBRATION...calibration is required every 28 days.". Review of VitD calibration records revealed the following calibrations were not performed every 28 days as required. a. Lot #921768 calibrated on 7/27/20, expired on 8/24/20, no documentation of calibration until 12/7/20, approximately 103 days after calibration expired. b. Lot #923068 calibrated on 4/10/21, expired on 5/8 /21, no documentation of calibration until 6/21/21, approximately 35 days after calibration expired. c. Lot #124241 calibrated on 7/21/21, expired on 8/18/21, no documentation of calibration until 11/17/21, approximately 90 days after calibration expired. 3. The laboratory failed to perform FT4 calibrations at the frequency required by manufacturer. Findings: Review of manufacturer's instructions for FT4 revealed on page 6, "CALIBRATION...calibration is required every 28 days.". Review of FT4 calibration records revealed the following calibrations were not performed every 28 days as required. a. The first calibration performed after testing began in January of 2020 was on 4/20/20, greater than approximately 75 days after testing began. b. Lot #922097 calibrated on 10/23/20, expired on 11/20/20, no documentation of calibration until 12/28/20, approximately 38 days after calibration expired. c. Lot #922166 calibrated on 2/1/21, expired on 3/1/21, no documentation of calibration until 3/24/21, approximately 23 days after calibration expired. d. Lot #922650 calibrated on 3/24/21, expired on 4/21/21, no documentation of calibration until 5/31/21, approximately 40 days after calibration expired. e. Lot #923009 calibrated on 5/31/21, expired on 6/28 /21, no documentation of calibration until 7/21/21, approximately 22 days after calibration expired. f. Lot #124064 calibrated on 7/21/21, expired on 8/18/21, no documentation of calibration until 11/29/21, approximately 90 days after calibration expired. 4. The laboratory failed to perform TSH3 calibrations at the frequency required by manufacturer. Findings: Review of manufacturer's instructions for TSH3 revealed on page 6, "CALIBRATION...calibration is required every 28 days.". Review of TSH3 calibration records revealed the following calibrations were not performed every 28 days as required. a. The first calibration performed after testing began in January of 2020 was on 4/20/20, greater than approximately 75 days after testing began. b. Lot #921655 calibrated on 6/11/20, expired 7/9/20, no documentation of calibration until 3/26/21, approximately 240 days after calibration expired. c. Lot #922957 calibrated on 3/26/21, expired on 4/23/21, no documentation

	of calibration until 5/31/21, approximately 36 days after calibration expired. d. Lot #124067 calibrated on 7/8/21, expired on 8/5/21, no documentation of calibration until 11/22/21, approximately 106 days after calibration expired. 5. The laboratory failed to perform PSA calibrations at the frequency required by manufacturer. Findings: Review of manufacturer's instructions for PSA revealed on page 7, "CALIBRATION...calibration is required every 28 days.". Review of PSA calibration records revealed the following calibrations were not performed every 28 days as required. a. The first calibration performed after testing began in January of 2020 was on 3/12/20, greater than approximately 60 days after testing began. b. Lot #921718 calibrated on 3/12/20, expired on 4/9/20, no documentation of calibration until 4/20 /20, approximately 11 days after calibration expired. c. Lot # 921817 calibrated on 4 /20/20, expired on 5/18/20, no documentation of calibration until 6/17/20, approximately 29 days after calibration expired. d. Lot #921818 calibrated on 6/17/20, expired on 7/15/20, no documentation of calibration until 7/27/20, approximately 11 days after calibration expired. e. Lot #921818 calibrated on 7/27/20, expired on 8/24 /20, no documentation of calibration until 2/17/21, approximately 165 days after calibration expired. f. Lot #922629 calibrated on 2/17/21, expired on 3/17/21, no documentation of calibration until 4/10/21, approximately 20 days after calibration expired. g. Lot #922938 calibrated on 4/10/21, expired on 5/8/21, no documentation of calibration until 6/18/21, approximately 40 days after calibration expired. h. Lot #923030 calibrated on 7/21/21, expired on 8/18/21, no documentation of calibration until 11/22/21, approximately 90 days after calibration expired.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of the AU480 Chemistry analyzer calibration records, absence of documentation, and interview with TP #2 on 5/19/22, the laboratory failed to perform 3-point calibration verifications every six months and failed to maintain documentation of all calibrations performed for the AU480 chemistry analyzer since testing began in July 2020, a period of approximately 22 months. Findings: The

	laboratory began testing on the Beckman Coulter AU480 for comprehensive metabolic profile, lipid profile, hemoglobin A1c(glycosylated hemoglobin). and a qualitative urine drug screen for Amphetamines, Barbiturate, Benzodiazepine, Cocaine, Cannabinoid, Opiates, Ecstasy, and Methadone in July 2020. 1. The laboratory failed to perform a 3-point calibration verification twice a year for chemistry testing on the AU480 since testing began in July 2020. Review of manufacturer's instructions and Chemistry calibration records revealed the laboratory uses a 2-point chemistry calibrator for CO2(Bicarbonate), Creatinine, Calcium, and uses a 1-point calibrator for Albumin, Total Bilirubin, Cholesterol, Glucose, Total Protein, Triglycerides, and BUN(Urea Nitrogen),HDL(high density lipoprotein) Cholesterol, Amphetamine, Barbiturate, Benzodiazepine, Cocaine, Cannabinoid, Opiates, Ecstasy, and Methadone. At approximately 2:45 p.m, TP#2 confirmed there was no documentation for calibration verifications on the AU480 chemistry analyzer. 2. The laboratory failed to maintain documentation of all calibrations performed for the AU480 since testing began. Review of records revealed a RB/Cal/QC log on file for 8/26/20-4/15/21. There was no calibration documentation from 4/15/21 to 11/22 /21. The calibration monitors on file since 11/22/21 did not reflect all calibrations performed for each analyte. For example: a. CO2 was calibrated on 11/29/21 with a calibration stability of 12/6/21. There was no documentation of a calibration for CO2 until 1/5/22(calibration monitor printed 1/6/22); b. Creatinine was calibrated on 11/29 /21 with a calibration stability of 12/6/21. There was no documentation of a calibration for Creatinine until 1/5/22; c. Albumin was calibrated on 11/22/21 with a calibration stability of 12/22/21. There was no documentation of calibration for Albumin until 12/27/21.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures, review of manufacturer's IFU's, review of Hematology and Chemistry QC, and absence of documentation 5/18/22 and 5/19/22, the laboratory failed to obtain two levels of acceptable QC each day of patient testing for CBC testing on the Abbott Cell-Dyn 1800 hematology analyzer and failed to document that at least two levels of QC was acceptable each day of patient testing on the AU480 chemistry analyzer since testing began in July 2020. Findings: A. Abbott Cell-Dyn 1800 The laboratory's "Cell-Dyn 1800 Hematology Analyzer" Policy states, "...Quality Control. Three(3) levels of control material will be processed each day prior to patient testing....11. If the results are in range, proceed with patient testing. NOTE: Control results outside of acceptable range will be flagged by the analyzer using 'L' for Low and 'H' for high....If 2 levels of control material are outside of acceptable range, ...9. Do not report patient results until acceptable quality control has been obtained...." Review of 2019, 2020, 2021, and 2022 Hematology QC revealed the laboratory failed to obtain two levels of acceptable QC on the Cell-Dyn 1800 for the following: a. January and February 2021- QC summary for low level only through 2/20/21; b. March, April, May, June 2021- no QC documentation on file for all analytes until 6/15/21; c. July 2021- Hemoglobin: 1 day in July 2021(7/17)-

	only low level acceptable; d. August 2021- MPV(mean platelet volume) 5 of 26 days (8/10, 8/11, 8/12, 8/24, 8/27)-only high level control was acceptable; e. September 2021- MPV: 3 of 23 days (9/1, 9/2, 9/29)- only high level control acceptable; f. October 2021- MPV: 3 of 24 days (10/6, 10/8, 10/23)- only high level control acceptable; g. January 2022- MPV: 9 of 22 days (1/4, 1/12, 1/13, 1/15, 1/18, 1/20, 1 /21, 1/22, 1/25)- only high level control acceptable; h. February 2022 - MPV: 13 of 23 days (2/1, 2/2, 2/3, 2/7, 2/8, 2/9, 2/10, 2/11, 2/14, 2/22, 2/24, 2/26, 2/28)- only high level control acceptable. Hemoglobin: 2 days(2/18, 2/21)- only high level acceptable; i. March 2022 -MPV: 16 of 27 days (3/2,3/3, 3/4, 3/5, 3/8, 3/9, 3/10, /11, 3/12, 3/16, 3 /17, 3/18, 3/19, 3/24, 3/28, 3/29)-only high level control acceptable; j. April 2022 - MPV: 11 of 29 days (4/2, 4/5, 4/14, 4/16, 4/19, 4/20, 4/23, 4/25, 4/26, 4/29, 4/30)- only high level control acceptable. Platelets: 1 day(4/5)- only low level acceptable. MCH(Mean Corpuscular Hemoglobin): 1 day(4/5)- only high level acceptable; k. May 2022 -MPV: 7 of 15 days (5/2, 5/5, 5/7, 5/11, 5/12, 5/13, 5/16)- only high level control acceptable. All analytes: 1 day(5/4)- only low level control tested. B. Beckman Coulter AU480 Online review of the Beckman Coulter AU manufacturer's IFU's for testing performed on the AU480 revealed for QC, " During operation of the Beckman Coulter AU analyzer, at least two levels of an appropriate quality control material should be tested a minimum of once a day. In addition controls should be performed after calibration with each new lot of reagent, and after specific maintenance or troubleshooting steps...". Review of 2020, 2021, and 2022 Chemistry QC records revealed the laboratory failed to document at least two levels of acceptable QC for the AU480 Chemistry analyzer since testing began in July 2020: a. There was no documentation of daily QC performed on the AU480 from the time testing began in July 2020 to January 2021. A QC monitor-Daily Chart(statistics) was on file for each analyte that showed the mean, SD(standard deviation), % CV (coefficient of variance), and range during that time-frame. Examples: For TBIL(total bilirubin) there was a QC monitor- daily chart on file for the 3 levels of MAS Chemtrak controls for the following: 8/1/20-8/28/20, 9/2/20-9/24/20, 10/1/20-10/30 /20, 11/2/20-11/30/20, 12/3/20-12/31/20, and 1/13/21-1/27/21; For Creatinine, there was a QC monitor-daily chart on file for the 3 levels of MAS Chemtrak controls for the following: 7/22/20-7/30/20, 8/1/20-8/28/20, 9/2/20-9/24/20, 10/1/20-10/30/20, 11 /2/20-11/30/20, 12/3/20, 12/31/20, 1/13/21-1/27/21. b. There was no Chemistry QC documentation after January 2021 until November 2021, when the laboratory began printing QC data for each analyte.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory records, review of manufacturer's instructions, review of Affirm VPIII QC and patient records, and interview with TP #2 on 5/18/22, the laboratory failed to establish an IQCP (Individualized Quality Control Plan) or perform and document positive and negative external controls each day of testing and failed to document positive and negative internal controls with each patient test. Findings: Review of laboratory records revealed the laboratory had an IQCP in place

	at the time of the last survey on 7/2/19, but it had not been reviewed, signed, and dated by the current laboratory director, and there was no documentation to indicate it had been used by the current staff. Manufacturer's instructions for the The BD Affirm VPIII Microbial Identification Test state on page 4 "...QUALITY CONTROL The BD Affirm VPIII Microbial Identification Test includes two internal controls on each PAC: a Positive Control bead and a Negative Control bead. These control beads are tested simultaneously with each patient specimen, ensuring the proper performance of PAC, Reagent Cassette (RC) and Processor. The Positive Control also ensures the absence of specimen interference. The Negative Control also ensures the absence of non-specific binding from the specimen. ... Review of Affirm VPIII patient logs revealed the only patient logs available were for patients tested 4/19/19 - 11/6/19, and patients tested 1/13/21 - 4/10/21. Internal positive and negative controls were documented for the 61 patients tested on these dates, but were not documented for any other patients tested. During interview at approximately 4:00 p.m., TP #2 stated that they do make sure positive and negative internal controls react appropriately for each patient test, but they do not document the internal control results. TP #2 stated they were unaware of the QC and patient logs provided by the manufacturer and they had not used them. The laboratory performs approximately 1560 Affirm VPIII tests per year.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of QC assay sheets, review of Access 2 QC records and interview with TP #2 on 5/18/22, the laboratory failed to verify QC assay ranges when a new lot number of QC was put into use. Findings: The laboratory uses Thermo Scientific MAS Liquimmune QC reagent for B12, FT4, TSH3, and PSA testing. The laboratory uses BIO-RAD Liquichek Specialty Immunoassay Control for VitD testing. The laboratory performs approximately 5720 tests per year on the Access 2 analyzer. Review of QC assay sheets and review of Access 2 QC records revealed QC ranges entered into the Access 2 database were incorrect for the following analytes and Lot numbers of QC: a. B12 - Lot #LlA24091 - IMMUNO-1 - Access 2 range - 177.6-272.8, QC assay sheet range - 167-250. Lot #LlA24092 - IMMUNO-2 - Access 2 range - 308.8-488.6, QC assay sheet range - 331-497. Lot #LlA24093 - IMMUNO-3 - Access 2 range - 528.6-840.0, QC assay sheet range - 503-755. b. FT4 - Lot #LlA24091 - IMMUNO-1 - Access 2 range - 1.115-1.385, QC assay sheet range - 0.89-1.34 Lot #LlA24092 - IMMUNO-2 - Access 2 range - 1.897-2.203, QC assay sheet range - 1.52-2.28 Lot #LlA24093 - IMMUNO-3 - Access 2 range - 3.188-3.812,

	QC assay sheet range - 2.84-4.28 c. TSH3 - Lot #LlA24091 - IMMUNO-1 - Access 2 range - 0.270-0.2730, QC assay sheet range - 0.20-0.30 Lot #LlA24092 - IMMUNO-2 - Access 2 range - 9.0-19.2, QC assay sheet range - 12.8-19.1 Lot #LlA24093 - IMMUNO-3 - Access 2 range - 24.589-33.211, QC assay sheet range - 24.0-36.1 d. PSA - Lot #LlA24091 - IMMUNO-1 - Access 2 range - 0.724-1.036, QC assay sheet range - 0.75-1.13 Lot #LlA24092 - IMMUNO-2 - Access 2 range - 1.405-4.375, QC assay sheet range - 2.40-3.60 Lot #LlA24093 - IMMUNO-3 - Access 2 range - 22.93-32.47, QC assay sheet range - 24.4-36.7 e. VitD - Lot #60281 - SPECIALTY-1 - Access 2 range - 10.312-29.212, QC assay sheet range - 10.7-23.3 Lot #60283 - SPECIALTY-3 - Access 2 range - 85.533-157.653, QC assay sheet range - 71.9-greater than (>) 120. Interview with TP #2 at approximately 4:30 p.m. confirmed the QC values entered into the Access 2 analyzer were incorrect. He stated he assumed they were correct because they had already been entered into the Access 2 database before he began employment in November of 2021.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on review of patient test reports, review of test requisitions and interview with TP #2 on 5/18/22, the laboratory failed to have a system for recording the date and time specimens were received from satellite facilities. Findings: Review of random patient test reports revealed the reports have a "Received Date" on the report. Review of random test requisitions for specimens received from satellite facilities revealed no documentation of the date and time specimens were received at the laboratory. Interview with TP #2 at approximately 2:15 p.m. confirmed the laboratory failed to have a system for recording the date and time specimens were received from satellite facilities. He stated the test report "Received Date" is the date the testing was resulted. He also stated they do not record the date and time specimens were received on the test requisitions.
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 review of manufacturer's instructions for use, review of laboratory's procedures, and review of random test reports 5/18/22 and 5/19/22, the test reports for Prostate Specific Antigen (PSA) fail to include the identity of the PSA assay used as required for interpretation and the test reports for Complete Blood Count(CBC) failed to reflect the reference ranges stated in the laboratory's procedures. Findings: 1.

	Review of manufacturer's IFU for PSA revealed "WARNING...The concentration of PSA in a given specimen determined with assays from different manufacturers can vary due to differences in assay methods and reagent specificity. The results reported by the laboratory to the physician must include the identity of the PSA assay used.". Review of random patient test report for PSA testing dated 5/18/22, patient date of birth 2/10/1949, revealed the test report failed to include the identity of the PSA assay. 2. Review of a random patient test report for CBC testing dated 5/17/22, for an adult female, revealed the following reference ranges that failed to reflect the reference ranges as stated in the laboratory's procedures. WBC(White blood cell): 4.1-10.9 x10^3/UL(microliter) Lymph %(lymphocytes percent): 4.1-58.5% Mono% (monocytes): 1.8-24.0% Neut%(Neutrophils): 7.8-92.0% RBC(Red Blood cell): 4.20-6.30 x10^6/UL HGB(Hemoglobin): 12.0-18.0 g(grams)/dL(deciliter) HCT (Hematocrit): 37.0-51.0% MCV(Mean corpuscular volume): 80.0-97.0fL(femtoLiter) MCH(Mean corpuscular hemoglobin): 26.0-32.0pg(picograms) MCHC(mean corpuscular hemoglobin concentration): 31.0-36.0g/dL RDW(red cell distribution width): 11.5-14.5% PLT(Platelets): 140-440 x10^3/UL MPV(mean platelet volume): 0.0-99.8fL Review of the laboratory's procedure "Cell-Dyn 1800 Hematology analyzer" revealed reference ranges as follows for an adult female: WBC 4.5-11.0 x10^3/UL Lymph% 25-40% Mono % 4-12% Gran % 50-73% RBC 4.0-5.2 x10^6/UL Hgb 12.0-15.0g/dL HCT 35.8-47.9% MCV 82-98fl MCH 26-34pg MCHC 31-37g/dL RDW 11.7-16.5% PLT 150-400 x10^3/UL MPV 5.9-9.4fl The laboratory's procedure "Hematology Policy & Procedure Complete Blood Count Test: Results & Normal Values" has different reference ranges listed for a female. For example: WBC 4,000-11,000cells/cu.mm(cubic millimeter) RBC 3.9-5.6 x10^6/cu.mm Hgb 11.5-16.5g% HCT 30-40% MCV 76-96um3(micrometer cubed) MCH 27-32pg MCHC 30-35% PLT 15,000-450,000cu.mm The reference ranges in the laboratory's procedures do not reflect the reference ranges stated on the test report (see D5403).
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of laboratory records, observation, and interview with testing personnel 5/18/22 and 5/19/22, the LD (laboratory director) failed to provide overall management and direction for the laboratory. Findings: 1. The LD failed to ensure the laboratory was enrolled in an HHS approved proficiency testing program for the 1st Hematology and Chemistry events in 2020 and for the subspecialty of Bacteriology in 2019, 2020, 2021, and 2022 (see D6015). 2. The LD failed to ensure a corrective action plan was followed when the laboratory received unacceptable proficiency testing results (see D6019). 3. The LD failed to ensure the quality control program was established and maintained to assure the quality of the testing performed (see D6020). 4. The LD failed to ensure the laboratory's established quality assessment program was maintained (see D6021). 5. The LD failed to ensure that patient test reports included pertinent information required for interpretation (see D6026). 6. The LD failed to ensure that 3 of 3 TP (#1, #2, #3) received appropriate training and had demonstrated that they could perform all testing operations reliably to report accurate patient test results for the Affirm VPIII and the Abbott Cell-Dyn 1800 (see D6029).

D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4) 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 CMS (Centers for Medicare and Medicaid Services) Casper report 155D and review of 2019, 2020, 2021, and 2022 API PT records 5/18/22, the LD failed to ensure the laboratory was enrolled in an HHS approved proficiency testing program for the 1st Hematology and Chemistry events in 2020 and for the subspecialty of Bacteriology in 2019, 2020, 2021, and 2022. Findings: Review of the CMS Casper report 155D revealed PT scores for the 2nd and 3rd events in 2020, but no scores for the 1st event for Hematology and Chemistry. Review of the laboratory's PT records revealed no documentation for the 2020 1st Hematology and Chemistry test events. Review of the CMS Casper report 155D and the laboratory's PT records revealed the laboratory failed to enroll for the subspecialty of Bacteriology in 2019, 2020, 2021, and 2022(See D2000).
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of 2019, 2020, 2021, and 2022 API PT records and absence of documentation 5/18/22, the LD failed to ensure a corrective action plan was followed when the laboratory received unacceptable PT results. Findings: Review of 2019, 2020, 2021, and 2022 API PT records revealed there was no corrective action documented for unacceptable PT results in 2019, 2020, and 2021. See the deficiency cited at D5221.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures, review of the laboratory's QC and calibration records, review of temperature and maintenance documentation, observation, and interview with TP #2 on 5/18/22 and 5/19/22, the LD failed to ensure the quality control program was established and maintained to assure quality of the testing provided. Findings: See the deficiency cited at D5400.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of laboratory procedure manual, review of 2019, 2020, 2021 and 2022 laboratory quality assessment (QA) records and interview with TP #2 on 5/18 /22, the LD failed to ensure the laboratory's established QA program was maintained since time of last survey, July 2, 2019 until November 18, 2021, a period of approximately 29 months in which QA activities were not performed as established. Findings: Review of laboratory procedure manual revealed the policy "Laboratory Assessment Policy" revealed "There are three steps involved in the Laboratory Quality and Performance assessment as follows: 1. Laboratory Weekly Assessment 2. Monthly QA and Maintenance Review 3. Laboratory Yearly Quality & Risk Assessment...". Review of laboratory procedure manual also revealed a "Daily Performance Review" form used to document daily QA activities. Review of daily QA records revealed the "Daily Performance Review" was not performed as established since time of last survey until January of 2022. There was no documentation of daily reviews for 7 of 7 months in 2019. There was no documentation of daily reviews for 12 of 12 months in 2020. Review of daily QA for 2021 indicated 8 daily reviews were performed, 6/16/21, 6/18/21, 11/18/21, 11/22/21, 11/23/21, 11/24/21, 11/29/21, and 11/30/21. Review of weekly and monthly QA records revealed the "Lab Director Weekly Assessment Report" and the "Laboratory Quality Assurance/Quality Control and Instrument Maintenance...Weekly and Monthly Review" was not performed as established for 7 of 7 months in 2019, for 12 of 12 months in 2020 and for 11 of 12 months in 2021. Interview with TP #2 at approximately 11:15 a.m. confirmed the laboratory QA program was not maintained as established. He stated he realized QA was not being performed when he began employment in November of 2021. He also stated that he began the QA activities at that time. This deficiency was cited on the previous survey 7/2/19.
D6026	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(8) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory

	director must-- (e)(8) Ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, review of laboratory procedures, and review of random patient test reports 5/18/22 and 5/19/22, the LD failed to ensure patient test reports included pertinent information required for interpretation. Findings: See the deficiency cited at D5807. This deficiency was cited on the previous survey 7/2/19.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of personnel records and interview with TP #2 on 5/18/22, the LD failed to ensure that 3 of 3 TP (#1, #2, #3) received appropriate training and had demonstrated that they could perform all testing operations reliably to report accurate patient test results for the Affirm VPIII and the Abbott Cell-Dyn 1800. Findings: 1. Review of personnel records for TP #1 and TP #2 revealed there were no training records available for the Affirm VPIII. Review of personnel records for TP #3 revealed a document which included a section titled "Affirm Skills Validation Training". TP #3 had initialed and dated the following items listed in the Affirm section: "Reagents, Performing Patient Analysis, Resulting Patient Samples, Documentation of patient results". TP #3 had not initialed and dated "QC info /frequency of QC", indicating that TP #3 had not been trained on Affirm quality control. During interview approximately 11:20-11:30 a.m., TP #2 stated that TP #1 trained him on the Affirm VPIII. He confirmed there was no documentation of training available for TP #1 and TP #2. He stated he trained TP #3 last week because the clinical consultant wants more people to be cross-trained. 2. Review of personnel records for TP #1 and TP #2 revealed the hematology training was labeled "Hematology Beckman Coulter Training". The hematology analyzer used by the laboratory is an Abbott Cell-Dyn 1800. There was no training documented for TP #1 and TP #2 for the Abbott Cell-Dyn 1800 hematology analyzer.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed.

	This CONDITION is not met as evidenced by: Based on review of personnel records 5/18/22 and the deficiency cited at D6065, the laboratory failed to verify that 1 of 4 testing personnel (TP #1) met the minimum education requirements for performing moderate complexity testing.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on review of personnel records and interview with TP #1 on 5/18/22, the laboratory failed to verify that 1 of 4 testing personnel (TP #1) met the minimum education requirements for performing moderate complexity testing. Findings: Review of personnel records for TP #1 revealed a resume which stated TP #1 had a diploma in medical assisting, Emergency Medical Technician diplomas for Basic and Paramedic programs, and a GED (General Education Development) diploma. There was no documentation of the GED in TP #1's personnel records. During interview at approximately 3:10 p.m., TP #1 stated she did not have a copy of her GED, but she might be able to get a copy from the medical assisting school she attended.