Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2295235	06/27/2024
Name of Provider or Supplier	**Street Address, City, State**	
Advanced Odessa Hospital & Clinics, Llc	900 E. 4th St, Odessa, TX	

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	The laboratory was surveyed and failed to meet the following conditions of the CLIA regulations found at CFR 42 493.1 through 493.1780: 493. 801 Condition: Enrollment and testing of samples; 493. 1250 Condition: Analytic Systems; 493. 1403 Condition: Laboratories Performing Moderate Complexity Testing; laboratory director; 493. 1421 Condition: Laboratories Performing Moderate Complexity Testing; testing personnel.
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: I. Based on observations, review of manufacturer's instructions and interview of facility personnel, the laboratory failed to store one of one box of Afinion 2 Hemoglobin A1C cartridges according to the manufacturer's instructions: The findings included: 1. Observations made during the inspection conducted June 25, 2024 at 10:57 AM found the Afinion 2 Hemoglobin A1C cartridges on the shelf above the analyzer. There was no date of opening or a new expiration date documented on the box of cartridges lot 10223685 expiration 2025-07-02. 2. Review of the manufacturer's instructions for use found on page 5 under the heading STORAGE AND STABILITY: "Refrigerated storage 2-8C (36-46F) The Afinion HbA1c Test Cartridges are stable until the expiration date only when stored refrigerated. The expiration date is stated on each foil pouch and on the kit box. The Afinion HbA1c Test Cartridge must reach a temperature of 18-30C (64-86F) before use. Upon removal from the refrigerator, leave the test cartridge in the unopened foil pouch for at least 15 minutes. No test result will be obtained if the test cartridge is too cold when used. An information code will be displayed. Room temperature storage 15-25C (59-

77F) The Afinion HbA1c Test Cartridges can be stored in unopened foil pouches at room temperature for 90 days. Note the date placed at room temperature and the new expiration date on the kit box. Avoid exposure to direct sunlight." 3. Review of patient test logs found the laboratory had tested four patient specimens for Hemoglobin A1C with cartridges stored at room temperature on the following dates: February 22, 2024 patient 422-I April 8, 2024 patient 623-I April 11, 2024 patient 644-I May 9, 2024 patient 769-I 4. During interview of testing person 6 on the CMS report 209 Laboratory Personnel Report conducted June 26, 2024 at 12:43 PM, he confirmed that the Hemoglobin A1C cartridges were stored on the shelf and not in the refrigerator since he started. II. Based on review of the package insert for the Afinion HbA1c Control, policies and procedures, review of A1C test logs, and interview of facility personnel , the laboratory failed to follow the manufacturer's instructions for performing quality control procedures. The findings included: 1. Review of the Afinion HbA1c controls (lot 92957814) instructions for use found under the heading Frequency of control testing: "Controls should be analyzed: with each new shipment of Afinion HbA1c DX Test Kits. with each new lot of Afinion HbA1c or Afinion HbA1c DX Test Kits. at least every 30 days. when training new operators in correct use of the Afinion HbA1c Test kit with the Afinion analyzer. anytime an unexpected result is obtained. Consult the package insert for the Afinion HbA1c test in use, section "Interpretation of results". 2. Review of the laboratory's own written policy titled Quality Control Policy (signed 11/8/23) found: "To ensure our laboratory systems are functioning properly, NO PATIENT RESULTS ARE TO BE REPORTED OUT without acceptable QC (quality control) being performed as detailed below: 4. AFINION A1c - Two levels of the Afinion QC have performed within the assayed range for A1c. This QC requirement is to be performed at least once per lot, per shipment, and every 30 days. 3. Review of laboratory test records found no documentation of two levels of quality controls being tested at least once every 30 days. 4. During interview of testing person 1 listed on the CMS Report 209 Laboratory Personnel Report conducted June 26, 2024 at 10:55 AM, she confirmed that the previous lab manager took care of the QC and she did not know where it was. 41687 III. Based on a review of the Siemens Multistix 10 SG package insert, surveyor observation, and staff interview, it was revealed that the laboratory failed to follow the manufacturer's instructions by ensuring one of one vial of Multistix reagent strips, used for urinalysis testing, included the open date. Findings include: 1. A review of the Siemens Multistix 10 SG package insert revealed the following: "Record the opening date on the label." 2. Surveyor observation of the laboratory on 6/26/24 at 3: 40 p.m. revealed a bottle of Multistix reagent strips (lot 309059, expiration date 3/31 /25) with no documentation of an open date. 3. In an interview on 6/26/24 at 3:45 p.m. in the laboratory, after review of the records, testing person #6 (as indicated on the CMS 209 form) confirmed the above findings. IV. Based on a review of the BD Veritor Plus Analyzer Instructions for Use, surveyor observation, the laboratory's records, and staff interview, the lab failed to follow the manufacturer's instructions by ensuring the BD Veritor Plus Analyzer was not exposed to a bright light for five of five months from February to June 2024. Findings include: 1. A review of the BD Veritor Plus Analyzer Instructions for Use revealed the following: "Summary of Cautions and Warnings - Ensure that the BD Veritor Plus Analyzer is not in direct sunlight or exposed to a bright light." 2. Surveyor observation of the laboratory on 6 /26/24 at 4:00 p.m. revealed the BD Veritor Plus Analyzer (Serial number: 2208302JBC8A0) was set on a countertop, underneath a bright under-cabinet halogen light. 3. A review of the laboratory's records revealed the laboratory estimated running 10 patient samples on the BD Veritor Plus Analyzer from February to June 2024. 4. In an interview on 6/26/24 at 4:05 p.m. in the laboratory, after review of the records, testing person #6 (as indicated on the CMS 209 form) confirmed the above findings.

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 a review of the American Proficiency Institute (API) 2024 Order Confirmation, the laboratory's policies and procedures, proficiency testing records, billing records, observations and interview of facility personnel, the laboratory failed to enroll and participate in a proficiency testing program for General Chemistry using a non-waived test method to test 239 patient specimens between February 2024 and June 24, 2024. The laboratory also failed to test 5 of 5 proficiency specimens in the same manner it tested patient specimens for the 2024 Hematology 1st event. The findings included: 1. Review of the American Proficiency Institute (API) 2024 Order Confirmation found the laboratory had enrolled in a proficiency testing program for Cardiac Makers and Hematology. 2. Review of the laboratory's own written procedure titled PROFICIENCY TESTING POLICY found: "It is the policy of this laboratory that all regulated analytes tested in-house require enrollment in HICFA approved proficiency testing (PT) program. The PT program will consist of three annual testing events with five challenges per analyte." 3. Review of billing records found the laboratory had tested 239 patient specimens for general chemistry analytes as follows: 213 patient specimens for Comprehensive Metabolic Panel (CMP) which include the following analytes: Sodium (Na) Potassium (K) Carbon Dioxide (CO2) Chloride (Cl) Glucose (Glu) Calcium (Ca) Blood Urea Nitrogen (BUN) Creatinine (Cre) Alkaline Phosphatase (ALP) Alanine Transaminase (ALT) Aspartate Transaminase (AST) Total Bilirubin (TBIL) Albumin (ALB) Total Protein (TP) 21 specimens for Basic Metabolic Panel (BMP) which include the following analytes: Sodium (Na) Potassium (K) Carbon Dioxide (CO2) Chloride (Cl) Glucose (Glu) Calcium (Ca) Blood Urea Nitrogen (BUN) Creatinine (Cre) 4 patient specimens for Lipid Panel which include the following analytes: Total Cholesterol (CHOL) High Density Lipoprotein (HDL) Triglycerides (TRIG) 1 patient specimen tested for General Chemistry 13 Panel which include the following analytes: Glucose (Glu) Calcium (Ca) Blood Urea Nitrogen (BUN) Creatinine (Cre) Alkaline Phosphatase (ALP) Alanine Transaminase (ALT) Aspartate Transaminase (AST) Total Bilirubin (TBIL) Albumin (ALB) Total Protein (TP) Gamma Glutamyl Transpeptidase (GGT) Uric Acid (UA) Amylase (AMY) 4. Review of proficiency testing records found the laboratory had participated in the 2024 Hematology 1st event, but failed to complete and retain the attestation form. There was no attestation page available for review for the 2024 Hematology 1st event. (See D 2009) The laboratory failed to test proficiency specimens in the same manner as patient specimens. Records showed the laboratory tested five of five proficiency samples twice in the Hematology 1st event. (See D 2010) 5. Observations of testing person 6 in the laboratory during the inspection conducted June 26, 2024 at 12:54 PM found him using a serum specimen to test patient 1023089 for CMP. 6. During interview of testing person 6 conducted June 26, 2024 at 12:54 PM, he confirmed that he only uses serum for testing patient specimens on the piccolo chemistry analyzer.

	During another interview conducted June 27, 2024 at 10:45 AM, testing person 6 confirmed that specimens to be tested for Complete Blood Counts (CBC) on the Medonic M series hematology analyzer were only tested once.
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 a review of the American Proficiency Institute (API) attestation forms, the laboratory's policies, the laboratory's API proficiency testing records from 2024, and staff interview, the laboratory failed to have documentation of the testing personnel and laboratory director signing one of one attestation statement in 2024. Findings include: 1. A review of the API attestation form revealed the following: "For all PT results, an attestation statement must be signed by testing personnel and the laboratory director and retained for a minimum of 2 years." 2. A review of the laboratory's policy titled 'Proficiency Testing Policy' revealed the following: "The PT attestation sheets must be signed by the testing personnel and lab director or designee and retained for two years." 3. A review of the laboratory's API proficiency testing records from 2024 revealed the attestation form for the following event was missing the testing personnel and laboratory director's signature: - 2024 Hematology/Coagulation 1st Event 4. In an interview on 6/27/24 at 11:30 a.m. in the phlebotomy drawing room, after review of the records, the CEO confirmed the above findings.
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, the laboratory's American Proficiency Institute (API) proficiency testing (PT) records from 2024, and staff interview, the laboratory failed to test proficiency testing samples in the same manner as it tested its patient samples for one of one PT event in 2024. Findings include: 1. A review of the laboratory's policy titled 'Proficiency Testing Policy' revealed the following: "The PT samples will be tested in the same manner as routine patient samples." 2. A review of the laboratory's API testing records from 2024 revealed the laboratory tested each of the five PT samples twice for the following testing event: - 2024 Hematology /Coagulation 1st Event 3. In an interview on 6/27/24 at 10:45 a.m. in the laboratory, after review of the records, testing person # 6 (as indicated on the CMS 209 form) confirmed the laboratory only tested patient samples once, therefore PT samples should have only been tested one time.
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 a review of the laboratory's policies, the laboratory's American Proficiency Institute (API) proficiency testing records from 2024, and staff interview, the laboratory failed to have documentation of the technical consultant evaluating the proficiency testing results for one of one event in 2024. Findings include: 1. A review of the laboratory's policy titled 'Proficiency Testing Assessment' revealed the following: "Whenever graded proficiency testing results are made available to the laboratory, they must be evaluated by the technical consultant ...The technical consultant will then document all the finding on the summary form provided by the PT program." 2. A review of the laboratory's API proficiency testing records from 2024 revealed the laboratory failed to have documentation of the technical consultant evaluating the proficiency testing results for the following event: - 2024 Hematology /Coagulation 1st Event 3. In an interview on 6/27/24 at 11:30 a.m. in the phlebotomy drawing room, after review of the records, the CEO confirmed the above findings.
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 a review of the laboratory's policies, surveyor observation, and staff interview, the laboratory failed to follow its policy two of six times by not including the time of collection on patient's blood specimen tubes. Findings include: 1. A review of the laboratory's policy titled 'Policy for Collecting, Labeling, and Preserving Patient Specimens' revealed the following: "It is the policy of this laboratory that all patient samples be labeled as follows: 1. All patient specimens will be labeled with the patient's first and last name and at least one other unique identifier such as DOB or medical record number. 2. All patient specimens will be labeled with the time and date of collection." 2. Surveyor observation of the laboratory's refrigerator on 6/26/24 at 10:05. a.m., revealed the blood specimen tubes for 6 patients were being stored after being tested by the laboratory. Further review of the specimen tubes revealed the following 2 patient's blood specimen tubes failed to include the time of collection: - Patient ID: 1004-1 Tested: 6/25/24 - Patient ID: 1008-1 Tested: 6/26/24 3. In an interview on 6/26/24 at 1:45 p.m. in the laboratory, after review of the records, testing person #1 (as indicated on the CMS 209 form) confirmed the above findings.
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 surveyor observations, review of the laboratories policies and procedures, quality control records, patient test records, and interview of facility personnel, the laboratory failed to meet the applicable analytic systems requirements for Chemistry and Hematology in 2024. Findings include: 1. The laboratory failed to have documentation of the current laboratory director signing and approving 18 of 18 policies used by laboratory personnel for testing in 2024. (See D5407) 2. The laboratory failed to follow the manufacturer's instructions for resolving flags on six of six patient's CBC (complete blood count) reports reviewed from the Medonic M-Series hematology analyzer. (See D5411) 3. The laboratory failed to ensure the Triage Total 5 Controls were stored at temperatures required by the manufacturer. (See D5413) 4. The laboratory failed to document the revised expiration dates on three of three Boule Con-Diff control vials used on the Medonic M-Series hematology analyzer in June 2024. (See D5415) 5. The laboratory failed to ensure the three levels of Boule Con-Diff controls had not exceeded their expiration date. (See D5417) 6. The laboratory failed to verify the performance specifications of the Abaxis piccolo Xpress chemistry analyzer, and the laboratory failed to have documentation of verifying the manufacturer's reference intervals prior to patient testing using the Medonic M- Series hematology analyzer and the Alere Triage Meter. (See D5421) 7. The laboratory failed to perform routine maintenance procedures on the two piccolo chemistry analyzers and the Medonic M-Series hematology analyzer as defined by the manufacturer for five of five months from February to June 2024. (See D5429) 8. The laboratory failed to establish and maintain a quality control program for Chemistry and Hematology. The laboratory failed to have a mechanism in place to ensure quality control procedures were tested each day of patient testing and monitor quality control values over time to detect shifts and trends for the Abaxis piccolo Chemistry analyzer, the Medonic M-Series hematology analyzer and the Alere Triage meter for five of five months from February to June 2024.(See D5441) 9. The laboratory failed to test at least two levels of quality control materials each each day of patient testing when using the Abaxis piccolo Xpress chemistry analyzer to test patient serum specimens and the laboratory failed to have documentation of running two levels of quality control (QC) material for the Cardiac and D-dimer cartridges run on the Alere Triage meter, each day of patient testing, from February to May 2024. (See D5547) 10. The laboratory failed to ensure quality control values were acceptable prior to reporting patient test results for Complete Blood Count (CBC) testing on the Medonic M-Series hematology analyzer. (See D5481)
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policy manual, the laboratory's records, and staff interview, the laboratory failed to have documentation of the current laboratory director signing and approving 18 of 18 policies used by laboratory personnel for testing in 2024. Findings include: 1. A review of the laboratory's policy manual

	revealed the current laboratory director failed to sign and approve the following 18 policies: - Laboratory Incident Management Plan - Policy for Collecting, Labeling, and Preserving Patient Specimens - Policy for Processing Patient Specimens - Specimen Acceptance and Rejection Policy - Instrument Calibration Policy - Quality Control Policy - Quality Control Assessment - Policy for Verifying Patient Results - Incorrect or Inconsistent Results Policy - Critical Decision Policy - Policy for Reporting Test Results - Record Retention Policy - Quality Assurance Policy - Policy for Verifying New Analytes and Methodologies - Proficiency Testing Assessment - Quality Assurance for Non-Regulated Analytes - Evaluation of Testing Personnel 2. A review of the laboratory's records revealed the current laboratory director was employed by the laboratory in May 2024. 3. In an interview on 6/26/24 at 10:00 a.m. in the phlebotomy drawing room, after review of the records, the CEO confirmed the above findings.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on a review of the Medonic M- Series User's Manual, the laboratory's policies, a random review of patient test records, and staff interview, the laboratory failed to follow the manufacturer's instructions for resolving flags on six of six patient's CBC (complete blood count) reports reviewed from the Medonic M- Series hematology analyzer from March to June 2024. Findings include: 1. A review of the Medonic M-Series User's Manual (1504472, February 2016) revealed the following: "The Medonic M- Series has several parameter and system information messages related to the measured parameters and the instrument. The messages are shown on the display and printouts. BL flag - The result is below linear range. Re-analyze the sample. BD flag - High interference between populations. Follow laboratory's protocol for verification of results. OM flag - Only one WBC population found. Follow laboratory's protocol for verification of results. TM flag - Too many WBC population found. Follow laboratory's protocol for verification of results." 2. A review of the laboratory's policies revealed the laboratory failed to define the steps for the laboratory personnel to follow for verifying flags on patient's CBC results. 3. A review of the laboratory's patient test records from March to June 2024 revealed the following 6 patients with flags present on the report: - Patient ID: 562-1 Run on 3/21 /24 TM flag present on LYM%, MID%, GRA%, LYM, MID, GRAN - Patient ID: 700-1 Run on 4/25/24 BD flag present on LYM%, MID%, GRA%, LYM, MID, GRAN - Patient ID: 748-2 Run on 5/17/24 OM flag present on LYM%, MID%, GRA%, LYM, MID, GRAN - Patient ID: 748-2 Run on 5/18/24 BD flag present on LYM%, MID%, GRA%, LYM, MID, GRAN - Patient ID: 849-1 Run on 5/27/24 BL flag present on PLT - Patient ID: 896-1 Run on 6/5/24 BD flag present on LYM%, MID%, GRA%, LYM, MID, GRAN 4. In an interview on 6/27/24 at 11:50 a.m. in the phlebotomy drawing room, after review of the records, the CEO confirmed the above findings. Key: WBC - white blood cell PLT - platelet LYM% - percent lymphocytes MID% - percent monocytes, basophils, eosinophils GRA% - percent granulocytes LYM - lymphocytes MID - monocytes, basophils, eosinophils GRAN - granulocytes

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:
I. Based on a review of the Triage Total 5 Control Product Insert, surveyor observation, a random review of the laboratory's Daily Refrige/Freezer Temperature Check logs from 2024, and staff interview, the laboratory failed to ensure the Triage Total 5 Controls were stored at temperatures required by the manufacturer for 20 of 20 days reviewed from February to June 2024. Findings include: 1. A review of the Triage Total 5 Control Product Insert (26601 Rev. A, 05/2018) revealed the following: "Store frozen at -20C or colder in a non-defrosting freezer." 2. Surveyor observation of the laboratory's freezer on 6/26/24 at 4:00 p.m. revealed the following boxes of controls inside: - 2 boxes of Triage Total 5 Control level 1 Lot number: C3969AN expiration date: 7/6/24 - 1 box of Triage Total 5 Control level 1 Lot number: C3996AN expiration date: 9/14/24 - 2 boxes of Triage Total 5 Control level 2 Lot number: C4001AN expiration date: 9/28/24 3. A random review of the laboratory's Daily Refrigerator/Freezer Temperature Check logs from 2024 revealed the following 20 dates when the temperature was recorded at a temperature warmer than -20C: Date: 2/4/24 Recorded temperature: 6 Date: 2/10/24 Recorded temperature: 2 Date: 2/20/24 Recorded temperature: 6 Date: 2/25/24 Recorded temperature: -4 Date: 3/2/24 Recorded temperature: 4 Date: 3/7/24 Recorded temperature: 4 Date: 3/16/24 Recorded temperature: 2 Date: 3/29/24 Recorded temperature: 2 Date: 4/6/24 Recorded temperature: -2 Date: 4/9/24 Recorded temperature: 0 Date: 4/17/24 Recorded temperature: -2 Date: 4/26/24 Recorded temperature: -4 Date: 5/5/24 Recorded temperature: 4 Date: 5/12/24 Recorded temperature: 3 Date: 5/20/24 Recorded temperature: 3 Date: 5/27/24 Recorded temperature: 2 Date: 6/1/24 Recorded temperature: 3 Date: 6/6/24 Recorded temperature: 3 Date: 6/11/24 Recorded temperature: 3 Date: 6/21/24 Recorded temperature: 3 4. In an interview on 6/26/24 at 3:00 p.m. in the laboratory, after review of the records, testing person #1 (as indicated on the CMS 209 form) confirmed the above findings. Key: C = degrees Celsius II. Based on surveyor observation, a review of the user's/operator's manuals for the laboratory's testing instrumentation, the laboratory's records, and staff interview, the laboratory failed to have documentation of monitoring the laboratory's room temperature and humidity for five of five months from February to June 2024. Findings include: 1. Surveyor observation of the laboratory on 6/26/24 at 9:30 a.m. found the following laboratory instrumentation being used for patient testing: a) Medonic M-Series analyzer (Serial number: 27294) b) Alere Triage meter (Serial number: 82559) c) Abbott i-STAT analyzer (Serial number: (21)421521) d) 2 Abaxis Piccolo Xpress analyzers (Serial numbers: P26481 and P22314) 2. A review of the user's/operator's manuals for the laboratory's instrumentation revealed the manufacturer required the following conditions for operation: a) Medonic M-Series User's Manual (1504472, February 2016) "Temperature 64 - 90F (18 - 32C) Humidity Up to 80%" b) Alere Triage MeterPro User Manual (2011) "Temperature 15 - 30C Humidity 10 - 85%" c) Abbott

	i-STAT System Manual (714336-00R, 10/18/21) "Operating Temperature 16 - 30C (61 - 86F) Relative Humidity 10 - 90% non-condensing" d) Piccolo Xpress chemistry analyzer Operator's Manual (1100-7108-1, Rev.E, 2020) "Ambient operating temperature 15 - 32C (59 - 90F) Humidity 8-80% relative humidity noncondensing" 3. A review of the laboratory's records from 2024 revealed the laboratory failed to have documentation of monitoring the room temperature and humidity in February, March, April, May, and June. 4. A review of the laboratory's records revealed the laboratory estimated performing 5,000 chemistry tests and 5,000 hematology tests annually. 5. In an interview on 6/27/24 at 11:50 p.m. in the phlebotomy drawing room, after review of the records, the CEO confirmed the above findings. Key: C = degrees Celsius F = degrees Fahrenheit III. Based on a review of manufacturer's instructions, surveyor observation, the laboratory's records, and staff interview, the laboratory failed to have documentation of monitoring the temperature in the Storage/Medication Room where laboratory supplies were stored for five of five months from February to June 2024. Findings include: 1. A review of the manufacturer's instructions for BD Vacutainer Blood Collection Tubes (2015) revealed the following conditions for tube storage: "4 - 25C" 2. A review of the manufacturer's instructions for Greiner Bio-One Vacuette Blood Collection Tubes revealed the following conditions for tube storage: "4 - 25C (40 - 77F)" 3. Surveyor observation of the Storage/Medication Room on 6/27/24 at 9: 15 a.m. revealed the following blood collection tubes being stored: - 15 Vacuette Coagulation Sodium Citrate 3.2% tubes - 1 Vacutainer Lithium Heparin tube - 23 Vacutainer Serum tubes - 60 Vacutainer SST tubes - 67 Vacuette K3 EDTA tubes - 69 Vacutainer Lithium Heparin tubes 4. A review of the laboratory's records from 2024 revealed the laboratory failed to have documentation of monitoring the temperature in the Storage/Medication Room for February, March, April, May, and June. 5. Further review of the laboratory's records revealed the laboratory estimated performing 5,000 chemistry tests and 5,000 hematology tests annually. 6. In an interview on 6/27/24 at 9:20 a.m. in the Storage/Medication Room, after review of the records, testing person #1 (as indicated on the CMS 209 form) confirmed the above findings. Key: C = degrees Celsius F = degrees Fahrenheit
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on a review of the CDS Boule Con-Diff Multi-Parameter Assayed Hematology Control Instructions for Use, surveyor observation, and staff interview, the laboratory failed to document the revised expiration dates on three of three Boule Con-Diff control vials used on the Medonic M-Series hematology analyzer in June 2024. Findings include: 1. A review of the CDS Boule Con-Diff Multi-Parameter Assayed Hematology Control Instructions for Use (PN 201078H R07.30.21) revealed the following: "Open vial stability 14 days." 2. Surveyor observation of the laboratory's refrigerator on 6/26/24 at 10:30 a.m. revealed the following 3 Boule Con-Diff control vials currently in use for the Medonic M-Series hematology analyzer with no documentation of a revised expiration date: Boule Con-Diff Low level Lot: 22404-01 Opened: 6/21/24 Boule Con-Diff Normal level Lot: 224404-02 Opened: 6/18/24

	Boule Con-Diff High level Lot: 22404-03 Opened: 6/18/24 3. In an interview on 6/27 /24 at 11:35 a.m. in the phlebotomy drawing room, after review of the records, the CEO confirmed the above findings.
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 a review of the Instructions for Use for the Boule Hematology Controls, a review of the laboratory's control records, a review of patient test records, and staff interview, the laboratory failed to ensure the three levels of Boule Con-Diff controls had not exceeded their expiration date for two of two testing days in June 2024. Findings include: 1. A review of the Instructions for Use for the Boule Hematology Controls (13679-6, 05/10/22) revealed the following: "When stored at 2-10 C, sealed vials are stable at least until the expiration date shown on the TABLE OF EXPECTED RESULTS." 2. A review of the laboratory's control records revealed the laboratory ran the following 3 levels of Boule Con-Diff controls on the Medonic M-Series hematology analyzer on the following dates and the controls had already exceeded their expiration date: Boule Con-Diff Low level Lot: 2240131 Expiration date: 6/10/24 Boule Con-Diff Normal level Lot: 2240132 Expiration date: 6/10/24 Boule Con-Diff High level Lot: 2240133 Expiration date: 6/10/24 - All three levels of controls were run on 6/11/24, 6/13/24 *Note: The analyzer flag 'EC - Expired Control' was printed on the bottom of each control print out. 3. A review of patient test records revealed the following patient specimens were run on the Medonic M-Series hematology analyzer on the days the controls had exceeded their expiration date: Date: 6/11/24 Patient ID: 933-1 Date: 6/13/24 Patient IDs: 936-1, 939-1 4. In an interview on 6/27/24 at 11:50 a.m. in the phlebotomy drawing room, after review of the records, the CEO confirmed the above findings.
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: I. Based on observations, review of laboratory records and interview of facility personnel, the laboratory failed to verify the manufacturer's claims of accuracy, precision, reportable range, and that the reference was appropriate for the patient population when using the Abaxis piccolo chemistry analyzers (serial numbers P26481 and P22314) to test 213 patient serum specimens for Comprehensive Metabolic Panel. The findings included: 1. Observations made during the inspection

	conducted June 26, 2024 at 12:54 PM found: a. The laboratory had 2 Abaxis piccolo chemistry analyzers (serial numbers P26481 and P22314) available for use. b. Testing person 6 removed a gold serum separator tube from the centrifuge and added the serum from specimen 1023089 into the CMP disc before loading it into piccolo SN P26481. c. Inventory of the laboratory refrigerator used to store reagents and specimens found the following discs available for use: 2 boxes Lipid Panel lot 4121AC2 (marked rec'd 6-13-24). one box contained 9 discs and the other contained 10 discs. 6 boxes Comprehensive Metabolic Panel discs lot 4132BAO expiration 2025-03-06. One box was open containing 5 of 10 discs, with 2 additional discs lying in the tray. 1 box Basic Metabolic Panel discs lot 4071AB4 expiration 2025-02-12, opened containing 9 of 10 discs. 2 boxes Basic Metabolic Panel discs lot 4071DB4 expiration 2025-02-12. 1 box Metlyte+ CRP discs lot 3521BA2 expiration 2024-12-18, opened containing 5 of 10 discs discs. 1 box General Chemistry 13 lot 351313B expiration 2025-06-13, opened containing 6 0f 10 discs. 2. Review of laboratory records found no verification of the manufacturers performance specifications available for review. 3. Review of patient test logs found in the notebook labeled PICCOLO found 152 patient labels for specimens tested using the piccolo. 4. During interview of testing person 6 conducted June 26, 2024 at 12:54 PM, he stated he only uses serum for testing patients. During interview of the technical consultant conducted June 27, 2024 at 9:40 AM, he confirmed that he did not perform verification studies for the Abaxis piccolo. 41687 II. Based on a review of the laboratory's policies, the laboratory's verification studies, the laboratory's test records, and staff interview, the laboratory failed to have documentation of verifying the manufacturer's reference intervals for two of two analyzers used for patient testing from February to June 2024. Findings include: 1. A review of the laboratory's policy titled 'Policy for Verifying New Instrumentation and Analytes' revealed the following: "It is the policy of this laboratory that all new moderate complex instrumentation and/or analytes must be validated prior to patient testing. Once these studies have been completed and deemed acceptable, the patient reference range must be established. This will generally be the ranges that are suggested by the manufacturer." 2. A review of the laboratory's verification studies for the Medonic M-Series hematology analyzer (Serial number: 27294) and the Alere Triage meter (Serial number: 82559) from February 2024 revealed the laboratory failed to have documentation of verifying the manufacturer's reference intervals prior to patient testing. 3. A review of the laboratory's records revealed the laboratory estimated performing 130 patient tests on the Medonic M-Series analyzer and 80 patient tests on the Alere Triage meter from February to June 2024. 4. In an interview on 6/27/24 at 11:40 a.m. in the phlebotomy drawing room, after review of the records, the CEO confirmed the above findings.
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: I. Based on observations, review of the Piccolo Xpress operator's guide, laboratory records and interview of facility personnel, the laboratory failed to perform and document weekly and semi-annual maintenance procedures on the 2 Abaxis Piccolo Xpress chemistry analyzers in 20 of 20 weeks between February 1, 2024 and June 26, 2024. The findings included: 1. Observations made during the inspection conducted

	June 26, 2024 at 11:10 AM found the air filters on both analyzers to be visibly dirty. 2. Review of the manufacturer's operator's guide found on page 9-1 under the heading Cleaning the Analyzer: "Clean the analyzer's external case and display at least weekly. Inspect the instrument casing during cleaning to ensure it is free of damage and cracks." Continued review found on page 9-2 under the heading Cleaning the Air Filter: "The air filter in the back of the analyzer should be cleaned at least twice per year. Check the air filter more often than twice per year if the analyzer is located in an environment with excessive dust or dirt." 3. During interview of testing person 6 on the CMS Report 209 Laboratory Personnel Report , he stated he never does maintenance and he did not have any maintenance logs. 41687 II. Based on a review of the Medonic M-Series User's Manual, the laboratory's records, and staff interview, the laboratory failed to have documentation of performing the required maintenance procedures on the Medonic M-Series hematology analyzer for five of five months from February to June 2024. Findings include: 1. A review of the Medonic M-Series User's Manual (1504472, February 2016) revealed the following: "This section contains information that is crucial for maintaining, transporting and storing the Medonic M-Series. - Daily Cleaning: Clean the aspiration and pre-dilute probes using an alcohol wipe. Remove possible traces of salt crystals or blood at the top of the aspiration and pre-dilute probes, probe rinse cup, and around the top of the sampling device probe inlet (if applicable) using a paper tissue with a disinfecting solution. - Monthly Cleaning: Clean the aspiration probes using an alcohol wipe. Fill a cup with 10 mL 2% hypochlorite (Bottle #2 from Boule Cleaning Kit) and one cup with 18 mL diluent. Aspirate the hypochlorite as a pre-dilute sample. Run 2 blank samples by aspirating diluent as a pre-diluted sample. Perform a background check, in pre-dilute mode, to verify all values are within range." 2. A review of the laboratory's records for 2024 revealed the laboratory failed to have documentation of performing the required daily and monthly maintenance procedures on the Medonic M-Series hematology analyzer for February, March, April, May, and June. 3. A review of the laboratory's testing records revealed the laboratory estimated performing 5,000 hematology tests annually. 4. In an interview on 6/27/24 at 11:47 a.m. in the phlebotomy drawing room, after review of the records, the CEO confirmed the above findings.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: I. Based on a review of the laboratory's policies, a review of the laboratory's test records from 2024, and interview of facility personnel, the laboratory failed to establish and maintain a quality control program for non-waived Chemistry testing using the Abaxis piccolo that would identify immediate errors and errors over time for five of five months from February to June 2024. The findings included: 1. A review of

	the laboratory's policy titled 'Quality Control Policy' revealed the following: "Piccolo - Two levels of QC have been performed within the assayed range for each analyte. This QC requirement is to performed at least once per lot, per shipment, and every 30 days." 2. Review of billing records found the laboratory had tested 239 patient specimens for general chemistry analytes as follows: 213 patient specimens for Comprehensive Metabolic Panel (CMP) which include the following analytes: Sodium (Na) Potassium (K) Carbon Dioxide (CO2) Chloride (Cl) Glucose (Glu) Calcium (Ca) Blood Urea Nitrogen (BUN) Creatinine (Cre) Alkaline Phosphatase (ALP) Alanine Transaminase (ALT) Aspartate Transaminase (AST) Total Bilirubin (TBIL) Albumin (ALB) Total Protein (TP) 21 specimens for Basic Metabolic Panel (BMP) Sodium (Na) Potassium (K) Carbon Dioxide (CO2) Chloride (Cl) Glucose (Glu) Calcium (Ca) Blood Urea Nitrogen (BUN) Creatinine (Cre) 4 patient specimens for Lipid Panel Total Cholesterol (CHOL) High Density Lipoprotein (HDL) Triglycerides (TRIG) 1 patient specimen tested for General Chemistry 13 Panel Glucose (Glu) Calcium (Ca) Blood Urea Nitrogen (BUN) Creatinine (Cre) Alkaline Phosphatase (ALP) Alanine Transaminase (ALT) Aspartate Transaminase (AST) Total Bilirubin (TBIL) Albumin (ALB) Total Protein (TP) Gamma Glutamyl Transpeptidase (GGT) Uric Acid (UA) Amylase (AMY) 3. Observations of testing person 6 in the laboratory during the inspection conducted June 26, 2024 at 12:54 PM found him using a serum specimen to test patient 1023089 for CMP. 4. During interview of testing person 6 conducted June 26, 2024 at 12:54 PM, he confirmed that he only uses serum for testing patient specimens on the piccolo chemistry analyzer and there were no quality control records available for review. 41687 II. Based on a review of the laboratory's policies, a review of the laboratory's quality control (QC) records from 2024, and staff interview, the laboratory failed to have a mechanism in place to monitor quality control values over time to detect shifts and trends for the Medonic M-Series hematology analyzer and the Alere Triage meter for five of five months from February to June 2024. Findings include: 1. A review of the laboratory's policy titled 'Quality Control Policy' revealed the following: "Medonic - At least two out of three levels of Boule Con-Diff control have performed within the assay range for each analyte on the day of testing and after any calibration. Alere Triage - Two levels of QC have been performed within the assay range for each analyte on each day of testing as well as the daily electronic QC." 2. A review of the laboratory's QC records from February to June 2024 revealed the laboratory failed to have a mechanism in place to monitor quality control values over time for the Medonic M-Series hematology analyzer and the Alere Triage meter. 3. In an interview on 6/27/24 at 11:40 a.m. in the phlebotomy drawing room, after review of the records, the CEO confirmed the above findings.
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: I. Based on a review of the laboratory's policies, a review of the laboratory's test records from 2024, and interview of facility personnel, the laboratory failed to test at least two levels of quality control material each day of patient testing using the Abaxis

piccolo to test 37 patient specimens using the CMP and BMP discs between June 1, 2024 and June 24, 2024. The findings included: 1. A review of the laboratory's policy titled 'Quality Control Policy' revealed the following: "Piccolo - Two levels of QC have been performed within the assayed range for each analyte. This QC requirement is to performed at least once per lot, per shipment, and every 30 days." 2. Review of billing records found the laboratory had tested 37 patient specimens for general chemistry analytes as follows: a. 35 patient specimens were tested for CMP on the following dates without at least two levels of quality control materials being tested: 06 /02/2024 - specimen 1020118 06/03/2024 - specimen 1020227 06/04/2024 - specimens 1019965, 1019951, 1020029, 1020496 and 1019952 06/05/2024 - specimens 102479, 102480,1020613 and 1020679 06/08/2024 - specimens 1020958 and 1021039 06/09/2024 - specimens 1021083, 1021131 and 1020983 06/11/2024 - specimen 1021428 06/13/2024 - specimens 1021628 and 1021702 06/14/2024 - specimen 1021885 06/16/2024 - specimen 1022058 06/18/2024 - specimens 1022287 and 1022296 06/19/2024 - specimens 1022342, 1022349, 102835, 1022418 and 1022439 06/20/2024 - specimens 102853 and 102855 06/21/2024 - specimens 1022628, 1022684 and 1022702 06/22/2024 - specimen 1022775 06/24/2024 - specimen 102914 b. 2 patient specimens were tested for BMP on the following dates without at least two levels of quality control materials being tested: 06/06/2024 - specimen 1020814 06/09/2024 - specimen 1020857 3. Observations of testing person 6 in the laboratory during the inspection conducted June 26, 2024 at 12:54 PM found him using a serum specimen to test patient 1023089 for CMP. 4. During interview of testing person 6 conducted June 26, 2024 at 12:54 PM, he confirmed that he only uses serum for testing patient specimens on the piccolo chemistry analyzer and there were no quality control records available for review. 41687 II. Based on a review of the laboratory's policies, the laboratory's quality control records, patient test records, and staff interview, the laboratory failed to have documentation of running two levels of quality control (QC) material for the Cardiac and D-dimer cartridges run on the Alere Triage meter, each day of patient testing, for nine of nine days reviewed from February to May 2024. Findings include: 1. A review of the laboratory's policy titled 'Quality Control Policy' revealed the following: "Alere Triage - Two levels of QC have been performed within the assay range for each analyte on each day of testing as well as the daily electronic QC." 2. A review of the laboratory's quality control records from February to May 2024 revealed the laboratory failed to have documentation of running 2 levels of QC material each day of patient testing for the following 9 days D-dimer and/or Cardiac cartridges (CK-MB and Troponin) were run on the Alere Triage meter: Date: 2/23/24- No documentation of 2 levels of QC run for D-dimer cartridge Date: 2/26/24- No documentation of 2 levels of QC run for D-dimer or Cardiac cartridges Date: 2/27/24- No documentation of 2 levels of QC run for D-dimer cartridge Date: 3/4/24- No documentation of 2 levels of QC run for D-dimer or Cardiac cartridges Date: 4/8/24- No documentation of 2 levels of QC run for Cardiac cartridge Date: 4/15/24- No documentation of 2 levels of QC run for Cardiac cartridge Date: 4/22/24- No documentation of 2 levels of QC run for Cardiac cartridge Date: 4/29/24- No documentation of 2 levels of QC run for Cardiac cartridge Date: 5/2 /24- No documentation of 2 levels of QC run for Cardiac cartridge 3. A review of patient test records revealed the following 12 patients were tested on days when the laboratory failed to have documentation of running 2 levels of QC material: Date: 2/23 /24 - Patient ID: 433-1 tested for D-dimer Date: 2/26/24 - Patient ID: 449-1 tested for D-dimer, CK-MB, Troponin Date: 2/27/24 - Patient ID: 455-1 tested for D-dimer Date: 3/4/24 - Patient ID: 479-1 tested for D-dimer, CK-MB, Troponin - Patient ID: 480-1 tested for D-Dimer, CK-MB, Troponin - Patient ID: 312-2 tested for D-dimer Date: 4/8/24 - Patient ID: 626-1 tested for CK-MB, Troponin Date: 4/15/24 - Patient ID: 601-2 tested for CK-MB, Troponin Date: 4/22/24 - Patient ID: 680-1 tested for

	CK-MB, Troponin Date: 4/29/24 - Patient ID: 719-1 tested for CK-MB, Troponin Date: 5/2/24 - Patient ID: 509-2 tested for CK-MB, Troponin - Patient ID: 734-1 tested for CK-MB, Troponin 4. In an interview on 6/27/24 at 11:50 a.m. in the phlebotomy drawing room, after review of the records, the CEO confirmed the above findings. Key: CK-MB = Creatine Kinase Myocardial Band
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, the laboratory's quality control records from February to June 2024, the laboratory's patient test records, and staff interview, the laboratory failed to ensure quality control values were acceptable prior to reporting patient test results for one of twenty days reviewed for Complete Blood Count (CBC) testing on the Medonic M-Series hematology analyzer. Findings include: 1. A review of the laboratory's policy titled 'Quality Control Policy' revealed the following: "To ensure our laboratory systems are functioning properly, NO PATIENT RESULTS ARE TO BE REPORTED OUT without acceptable QC being performed as detailed below: 1. MEDONIC- At least two out of three levels of BOULE CON-DIFF control have performed within the assay range for each analyte on the day of testing and after any calibration." 2. A random review of quality control records from February to June 2024 revealed the following day when 2 levels of quality control (QC) were run and only one level performed within the assay range: Date: 5/23/24 Boule Con-Diff Normal Control lot number: 2240102 - all values within the assay range Boule Con-Diff High Control lot number: 2240103 - Lym and RBC values were below the assay range *The laboratory failed to have documentation of the Boule Con-Diff Low Control being run on 5/23/24. 3. A review of the laboratory's patient test records revealed the following patient was run on 5/23/24, when only one level of QC was within the assay range: Patient ID: 836-1 4. In an interview on 6/27/24 at 11:30 a.m. in the phlebotomy drawing room, after review of the records, the CEO confirmed the above findings. Key: LYM = Lymphocytes RBC = Red Blood Cells
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 upon review of policies and procedures, quality control records, patient test records, quality assurance reports and interview of facility personnel, the laboratory director failed to provide oversight and direction of the moderate complexity laboratory performing Chemistry and Hematology testing in 2024. 1. The laboratory director failed to ensure pre-analytic and analytic systems provided quality results for testing in 2024. (See D6007) 2. The laboratory director failed to ensure verification

	studies were complete for three of three analyzers used for nonwaived patient testing from February to June 2024. (See D6013) 3. The laboratory director failed to ensure proficiency testing samples were tested in the same manner as patient samples for one PT event in 2024. (See D6016) 4. The laboratory director failed to ensure the proficiency testing results for one event in 2024 was evaluated. (See D6018) 5. The laboratory failed to test at least two levels of Hematology and Chemistry quality control materials prior to testing patient specimens. (See D6020) 6. The laboratory quality assurance program failed to identify that patient specimens were tested and reported without testing at least two level of quality control materials. (See D6021) 7. The laboratory director failed to ensure two of six testing personnel met minimum education requirements and had received appropriate training before testing patient specimens in Hematology. (See D6065 and D6066)
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) 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)(1) 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 a review of the laboratory's policies, the laboratory's records, and staff interview, the laboratory director failed to ensure pre-analytic and analytic systems provided quality results for testing in 2024. Findings include: 1. The laboratory failed to follow its policy two of six times by not including the time of collection on patient's blood specimen tubes. (See D5311) 2. The laboratory failed to have documentation of the current laboratory director signing and approving policies used by laboratory personnel for testing in 2024. (See D5407) 3. The laboratory failed to follow the manufacturer's instructions for resolving flags on patient's CBC (complete blood count) reports reviewed from the Medonic M- Series hematology analyzer. (See 5411) 4. The laboratory failed to ensure the Triage Total 5 Controls were stored at temperatures required by the manufacturer. (See D5413 I) 5. The laboratory failed to have documentation of monitoring the laboratory's room temperature and humidity. (See D5413 II) 6. The laboratory failed to document the revised expiration dates on three of three Boule Con-Diff control vials used on the Medonic M-Series hematology analyzer. (See D5415) 7. The laboratory failed to ensure the three levels of Boule Con-Diff controls had not exceeded their expiration date. (See D5417) 8. The laboratory failed to have documentation of performing the required maintenance procedures on the Medonic M-Series hematology analyzer. (See D5429)
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, the laboratory's verification studies, the laboratory's test records, and staff interview, the laboratory director failed to ensure verification studies were complete for two of two analyzers used for patient testing from February to June 2024. Findings include: 1. The laboratory failed to have documentation of verifying the manufacturer's reference intervals for two of two analyzers used for patient testing. (See D5421)
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, the laboratory's American Proficiency Institute (API) proficiency testing (PT) records, and staff interview, the laboratory director failed to ensure proficiency testing samples were tested in the same manner as patient samples for one of one PT event in 2024. (See D2010)
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(iii) Ensure that 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 a review of the laboratory's policies, the laboratory's American Proficiency Institute (API) proficiency testing records from 2024, and staff interview, the laboratory director failed to ensure the proficiency testing results for one of one event in 2024 was evaluated. (See D5211)
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 upon review of policies and procedures, quality control records, patient test records and interview of facility personnel, the laboratory director failed to establish and maintain a quality control program for non-waived testing in Chemistry and Hematology prior to testing patient specimens. (See D5441, D5447, D5481)
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 upon review of policies and procedures, quality control records, patient test records, and interview of facility personnel, the laboratory quality assurance program failed to identify that 78 patient specimens were tested and reported on 10 of sixty one days in August and September of 2023 without testing at least two level of quality control materials. (See D 5791)
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 the CMS Report 209 Laboratory Personnel Report, personnel records and interview of facility personnel found the laboratory director failed to ensure two of six testing personnel met minimum education requirements and had received appropriate training before testing patient specimens in Hematology. (See D 6065 and D6066)
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 the CMS Report 209 Laboratory Personnel Report, personnel records and interview of facility personnel found that two of six testing personnel failed to have documentation of education and initial training for performing moderate complexity testing in Hematology and Chemistry . The findings included: 1. Review of the CMS report 209 Laboratory Personnel Report identified six testing personnel performing moderately complex testing. 2. Review of personnel records found no documentation of education for testing person four (hire date requested but not provided) and no evaluation of foreign credentials or documentation of training for testing person six (hire date requested but not provided) 3. During interview of the Human resources person conducted June 27, 2024 at 09:37 AM, she confirmed that all education and training records were in the employee files found in the drawer of the filing cabinet.
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 the CMS Report 209 Laboratory Personnel Report, personnel records and interview of facility personnel found that two of six testing personnel failed to have documentation of education for performing moderate complexity testing in Hematology and Chemistry . The findings included: 1. Review of the CMS report 209 Laboratory Personnel Report identified six testing personnel performing moderately complex testing. 2. Review of personnel records found no documentation of education for testing person four (hre date requested but not provided), and no foreign credential evaluation of education for testing person six (hire date requested but not provided). 3. During interview of the Human resources person conducted June 27, 2024 at 09:37 AM, she confirmed that all education and training records were in the employee files found in the drawer of the filing cabinet.
D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens.

	This STANDARD is not met as evidenced by: Based on review of the CMS Report 209 Laboratory Personnel Report, personnel records and interview of facility personnel found that one of six testing personnel failed to have documentation of initial training for performing moderate complexity testing in Hematology and Chemistry . The findings included: 1. Review of the CMS report 209 Laboratory Personnel Report identified six testing personnel performing moderately complex testing. 2. Review of personnel records found no documentation of training for testing person six (hire date requested but not provided) 3. During interview of the Human resources person conducted June 27, 2024 at 09:37 AM, she confirmed that all education and training records were in the employee files found in the drawer of the filing cabinet.