Department of Health & Human Services
Centers for Medicare & Medicaid Services

Form Approved
OMB No. 0938-0391

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number	(X3) Date Survey Completed
	26D1094558	08/22/2024
Name of Provider or Supplier	**Street Address, City, State**	
St Louis Medical Professionals	8790 Watson Rd, Suite 100, Saint Louis, MO	
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	A recertification survey was completed on August 22, 2024. It was determined that Immediate Jeopardy (IJ) existed for the following condition level deficiencies: 42 C.F. R. 493.1250 Condition: Analytic Systems 42 C.F.R. 493.1403 Condition: Laboratory Director
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 the Siemens Clinitek Status manufacturer's instructions, observation of the Osom strep kit, review of the Abbott Afinion AS100 analyzer, lack of quality control (QC) documentation, and interview with the laboratory director, the laboratory failed to follow manufacturer's instructions for performing Clinitek Status urinalysis testing, Osom strep kit testing and hemoglobin A1c (HbA1c) testing. Findings: 1. Review of the Siemens Clinitek Status urinalysis analyzer manufacturer instructions states, "Test negative and positive controls whenever a new bottle of reagent strips is first opened." 2. Review of urinalysis strips revealed Siemens multistix 10SG lot # 303030 expiration date 9/30/24 in use. 3. Review of Siemens Clinitek Status urinalysis analyzer QC revealed the laboratory could not provide QC from July 28, 2022 to date August 20, 2024. 4. Observation of the waived tests kits revealed Osom strep kit lot # 221273 expiration 12/31/23 still in use. The laboratory was unable to provide the number of patient tests performed while the Osom strep kit was expired. 5. Review of Afinion HbA1c manufacturer's instructions states "Controls should be analyzed: with each new shipment of Afinion HbA1c test kits, with each new lot of Afinion HbA1c tests kits and at least every 30 days". 6. Review of Afinion HbA1c QC showed no QC performed in June 2024, July 2024 and August 2024. 7.

	Review of Afinion HbA1c manufacturer's instructions states "Opened control vials are stable for 60 days when stored refrigerated 2-8 degrees Celsius." 8. Observation of HbA1c QC showed lot # 902958609 opened 5/17/24, expired 7/17/24. One patient performed on August 19, 2024 with expired QC. 9. Interview with the laboratory director on August 20, 2024 at 11:00 AM confirmed the laboratory failed to follow manufacturer's instructions for performing Clinitek Status urinalysis testing, strep testing and hemoglobin A1c (HbA1c) testing.
D2003	ENROLLMENT CFR(s): 493.801(a)(2)(ii) For those tests performed by the laboratory that are not included in subpart I of this part, a laboratory must establish and maintain the accuracy of its testing procedures, in accordance with 493.1236(c)(1) This STANDARD is not met as evidenced by: Based on interview with the laboratory director (LD), review of proficiency testing records for 2022, 2023, and to date August 20, 2024, and interview with the testing personnel (TP) #2, the laboratory failed to establish a means to verify the accuracy for urine microscopic testing twice a year in 2022, 2023 and to date August 20, 2024. Findings: 1. Interview with the laboratory director (LD) on August 20, 2024 at 10:30 AM, the LD states that "he performs urine microscopic testing occasionally or as needed." 2. Review of proficiency testing records for 2022, 2023, and to date August 20, 2024, showed the laboratory failed to prove accuracy on the non-regulated analyte urine microscopic testing. 3. Interview with the TP #2 on August 20, 2024 at 11:00 AM confirmed the laboratory failed to establish a means to verify the accuracy of urine microscopic testing twice a year.
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 observation of two microscopes, observation of laboratory and laboratory refrigerators, laboratory procedures, temperature logs, review of the Cell-Dyn 22 Plus Control quality control (QC) package insert, observation of the Cell-Dyn 22 Plus hematology QC vials, observation of room temperature supplies, review of the Olympus AU400 chemistry analyzer maintenance logs, lack of documentation for function checks, review of the Abbott Cell-Dyn Emerald 22 AL hematology analyzer operator's guide, review of calibration records for the Abbott Cell-Dyn Emerald 22 AL hematology analyzer, patient results, review of calibration records for the Olympus AU400 chemistry analyzer, lack of Olympus AU400 chemistry analyzer patient logs, lack of Access 2 chemistry analyzer patient logs, Olympus AU400 chemistry analyzer QC, Access 2 chemistry analyzer QC, lack of Abbott Cell-Dyn Emerald 22 AL hematology patient logs, review of Abbott Cell-Dyn Emerald 22 AL

	hematology analyzer QC, and interviews, the laboratory failed to meet the condition of analytic systems. The laboratory failed to document microscope maintenance (Refer to D5411); the laboratory failed to ensure room temperature, refrigerator temperature, freezer temperature and humidity was taken every day (Refer to D5413); the laboratory failed to document expiration date on hematology QC (Refer to D5415); the laboratory failed to ensure the laboratory's reagents, quality control and supplies were not used when they had exceeded their expiration date (Refer to D5417); the laboratory failed to perform and document maintenance for the Olympus AU400 chemistry analyzer, (Refer to D5429); the laboratory failed to define, perform and document function checks for laboratory centrifuges (Refer to D5435); the laboratory failed to follow manufacturer's recommended frequency for calibration verification of the hematology analyzer (Refer to D5437); the laboratory failed to perform calibration verification procedures at least once every six months that included at least a minimal value, a mid-point value, and a maximum value near the upper limit to verify the laboratory's reportable range (Refer to D5439); the laboratory failed to include two controls materials of different concentrations each day of patient testing for chemistry and hematology testing (Refer to D5447).
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: Observation of 2 microscopes and interview with the laboratory director (LD), the laboratory failed to document microscope maintenance for 2022 to date August 20, 2024. Findings: 1. Observation of 2 of 2 microscopes showed no documentation of maintenance for 2022 to date August 20, 2024. 2. Interview with the LD on August 20, 2024 at 11:00 AM confirmed the laboratory failed to document microscope maintenance.
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 observation of the laboratory, review of temperature logs, observation of refrigerator, Cell-Dyn Emerald hematology analyzer procedure, and interview with the laboratory director, the laboratory failed to monitor and document the temperature of room, refrigerator, freezer and humidity. Findings: 1. Observation of laboratory revealed a Cell-Dyn Emerald hematology analyzer. 2. Review of Cell-Dyn Emerald

	hematology analyzer procedure states "To ensure the instrument and reagents function properly, it is important to maintain the temperature between 18 degrees Celsius to 32 degrees Celsius". 3. Review of room temperature log located in the laboratory showed no documentation of room temperature for 142 of 233 days in 2024. 4. Review of Cell-Dyn Emerald hematology analyzer procedure states "Maximum relative humidity 80% for temperatures up to 32 degrees Celsius". 5. Review of humidity log located in the laboratory showed no documentation of humidity for 142 of 233 days in 2024. 6. Observation of the urgent care room refrigerator revealed Cell-Dyn22 plus controls lot # MLH4183 expiration 9/13/24 temperature range 2 degrees Celsius to 8 degrees Celsius. 7. Review of refrigerator temperature log located in the urgent care room showed no documentation of refrigerator temperature for 153 of 233 days in 2024. 8. Review of freezer temperature log located in the urgent care room showed no documentation of freezer temperature for 158 of 233 days in 2024. 9. Interview with the laboratory director on August 20, 2024 at 11:00 AM confirmed the laboratory failed to ensure temperature logs were documented.
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 review of the Cell-Dyn 22 Plus Control quality control (QC) package insert, observation of the Cell-Dyn 22 Plus hematology QC vials and interview with the testing personnel (TP) #2, the laboratory failed to document open and expiration dates on hematology QC. Findings: 1. Review of the Cell-Dyn 22 Plus Control QC package insert states "8 Consecutive Day Open-Vial Stability." 2. Observation of opened Cell-Dyn 22 Plus hematology QC vials lot # L4183, N4183 and H4183 showed no open and expiration dates on QC vials. 3. Interview with the TP #2 on August 20, 2024 at 10:00 AM confirmed the laboratory failed to document open and expiration dates on hematology QC.
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 observation of the laboratory's refrigerators, room temperature supplies and interview with the testing personnel (TP) #2, the laboratory failed to ensure the laboratory's reagents, quality control and supplies were not used when they had exceeded their expiration date. Findings: 1. Observation of the laboratory refrigerators showed reagents still in use: 1 box of Clean Chem Diagnostics Inc. Direct Bilirubin lot # 2238 expiration date 10/01/2023 1 box of Clean Chem Diagnostics Inc. Cholesterol, Total lot # 216501-120 expiration date 01/01/2024 1 box of Clean Chem

	Diagnostics Inc. Carbon Dioxide (CO_2) lot # 303901-025 expiration date 06/01/2024 1 box of Clean Chem Diagnostics Inc. Aspartate Aminotransferase (AST) lot # 218601-117 expiration date 02/01/2024 2. Observation of the laboratory's room temperature supplies showed reagents, quality control material and supplies still in use: 1 bottle of Beckman Coulter Contrad 70 lot # 803520 expiration date 05/04/2023 1 bottle of Beckman Coulter Citranox lot # C9E1 expiration date 05/31/2023 1 bottle of Beckman Coulter Access Wash Buffer II lot # 331861F expiration date 10/07/2023 1 box of Beckman Coulter ISE Low Serum Standard lot # 2694 expiration date 07/19 /2022 1 box of Beckman Coulter ISE High Serum Standard lot # 2697 expiration date 06/01/2022 9 Hologic Aptima Unisex Swab Collections kits lot # 286753HA expiration date 03/31/2022 5 UTM-RT w/o beads collection kits lot # B103746 expiration date 02/28/2023 10 BD Vacutainer, Urinalysis Transfer Straw kits lot # 2096183 expiration date 10/2023 1 box of Direct Enzymatic HbA1C Assay Control set lot # HBC001220-01-02 expiration date 11/29/2023 1 box of Direct Enzymatic HbA1C Assay Calibrator set lot # HBS003220-01-09 expiration date 06/08/2024 43 BD Vacutainer Serum tubes lot # 3059371 expiration date 06/30/2024 4 bottles of Thermo Scientific VersaTrek Redox 2 aerobic blood culture bottles 4 bottles of Thermo Scientific VersaTrek Redox 2 anaerobic blood culture bottles 3. Interview with the testing personnel (TP) #2 on August 20, 2024 at 11:00 AM confirmed the laboratory failed to ensure the laboratory's reagents, quality control material and supplies were not used when they had exceeded their expiration date.
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 Olympus AU400 chemistry analyzer manufacturer maintenance logs and interview with the lab director (LD), the laboratory failed to perform and document maintenance for the Olympus AU400 chemistry for 2023 to date chemistry testing was discontinued in February 2024. Findings: 1. Review of the Olympus AU400 chemistry analyzer manufacturer maintenance logs showed no documentation of maintenance for "monthly analyzer" maintenance for April 2023, May 2023, August 2023, September 2023, October 2023, November 2023 and January 2024. 2. Review of the Olympus AU400 chemistry analyzer manufacturer maintenance logs showed no documentation of maintenance for "every three months analyzer and every three months ISE" maintenance for 2023 to date testing was discontinued in February 2024. 3. Interview with the LD on August 20, 2024 at 11:00 AM confirmed, the laboratory failed to perform and document maintenance for the Olympus AU400 chemistry analyzer.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result

	reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on lack of documentation for function checks and interview with the testing personnel (TP) #2, the laboratory failed to define, perform and document function checks for 2 of 2 laboratory centrifuges in 2022, 2023 and to date August 20, 2024. Findings: 1. Lack of function check documentation showed the laboratory failed to define, perform and document function checks for the Unico Powerspin FX centrifuge and the Fisher Healthcare Horizon model 642E centrifuge in 2022, 2023 and to date August 20, 2024. 2. Interview with the testing personnel (TP) #2 on August 20, 2024 at 10:30 AM confirmed that the laboratory failed to define, perform and document function checks for the laboratory's centrifuges.
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 the Abbott Cell-Dyn Emerald 22 AL hematology analyzer operator's guide, 2022/2023/2024 calibration records for the Abbott Cell-Dyn Emerald 22 AL hematology analyzer, patient results and interview with the testing personnel (TP) #2, the laboratory failed to follow manufacturer's recommended frequency for calibration verification of the hematology analyzer in 2022 and to date August 20, 2024. Findings: 1. Review of the Abbott Cell-Dyn Emerald 22 AL hematology analyzer operator's guide states "When to Calibrate, Calibration verification criteria include: At least every six months." 2. Review of 2022, 2023, and 2024 calibration records for the Abbott Cell-Dyn Emerald 22 AL hematology analyzer showed the laboratory failed to perform a calibration verification following manufacturer's recommended frequency of every six months in 2022, 2023 and to date August 20, 2024 for the analytes: white blood cell, red blood cell, hemoglobin, hematocrit and platelet. 3. The laboratory was unable to provide the number of hematology tests that they perform per year. 4. Interview with the TP #2 on August 20, 2024 at 10:00 AM confirmed the laboratory failed to follow manufacturer's recommended frequency of every six months for calibration of the Abbott Cell-Dyn Emerald 22 AL hematology analyzer.
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 2022, 2023, and to date August 20, 2024 calibration records for the Olympus AU400 chemistry analyzer and interview with the laboratory director (LD), the laboratory failed to perform calibration verification procedures at least once every six months that included at least a minimal value, a mid-point value, and a maximum value near the upper limit to verify the laboratory's reportable range for 22 of 22 analytes. Findings: 1. Review of Olympus AU400 chemistry calibration records for 2022, 2023, and to date August 20, 2024 showed no calibration every six months that included at least a minimal value, a mid-point value, and a maximum value near the upper limit to verify the laboratory's reportable range for the analytes: albumin, alkaline phosphatase, aspartate aminotransferase, alanine transaminase, direct bilirubin, total bilirubin, blood urea nitrogen, calcium, chloride, cholesterol, CO_2, creatine kinase, creatinine, glucose, high-density lipoprotein, low-density lipoprotein, magnesium, phosphorus, potassium, sodium, total protein and triglycerides. 2. Interview with the LD on August 20, 2024 at 11:00 AM confirmed the laboratory failed to perform calibration verification procedures at least once every six months that included at least a minimal value, a mid-point value, and a maximum value near the upper limit to verify the laboratory's reportable range.
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 laboratory procedures, lack of Olympus AU400 chemistry analyzer patient logs, lack of Access 2 chemistry analyzer patient logs, Olympus

	AU400 chemistry analyzer quality control (QC), Access 2 chemistry analyzer QC, patient results and interview with the laboratory director (LD), the laboratory failed to include two controls materials of different concentrations each day of patient testing. Findings: 1. Review of "The Olympus AU400" procedure states "During operation of the AU400/AU400e, at least two levels of control material should be tested a minimum of once a day". 2. Lack of Olympus AU400 chemistry analyzer patient logs revealed the laboratory could not provide dates of patient testing from June 2022 to February 2024 when patient testing ceased. 3. Review of Olympus AU400 QC showed the laboratory could not provide documentation for QC performed each day of patient testing for the analytes: albumin, alkaline phosphatase, aspartate aminotransferase, alanine transaminase, direct bilirubin, total bilirubin, blood urea nitrogen, calcium, chloride, cholesterol, CO_2, creatine kinase, creatinine, glucose, high-density lipoprotein, low-density lipoprotein, magnesium, phosphorus, potassium, sodium, total protein and triglycerides. 4. Review of the "Quality Control Materials" procedure states "Instruments that require 3 quality control, 2 out of 3 controls must pass before performing patient tests". 5. Review of Access 2 chemistry analyzer patient logs revealed the laboratory could not provide dates of patient testing from June 2022 to October 2023 when patient testing ceased. 6. Lack of Access 2 QC showed the laboratory could not provide documentation for QC performed each day of patient testing for the analytes: prostate specific antigen, thyroid stimulating hormone, and Free T4. 7. The laboratory was unable to provide the volume of patient tests performed on the Olympus AU400 chemistry analyzer and Access 2 chemistry analyzer while QC was not performed. 8. Interview with the LD on August 20, 2024 at 11:00 AM confirmed the laboratory failed to include two controls materials of different concentrations each day of patient testing on the Olympus AU400 chemistry analyzer and Access 2 chemistry analyzer. 44735 Based on review of laboratory procedures, lack of Abbott Cell-Dyn Emerald 22 AL hematology patient logs, review of Abbott Cell-Dyn Emerald 22 AL hematology analyzer quality control (QC), and interview with the testing personnel (TP) #2, the laboratory failed to include two controls materials of different concentrations on the Abbott Cell-Dyn Emerald 22 AL hematology analyzer each day of patient testing. Findings: 1. Review of laboratory procedure "Quality Control Materials" states "Quality control materials must be performed each day of use." 2. Lack of Abbott Cell-Dyn Emerald 22 AL hematology patient logs showed the laboratory could not provide dates of patient testing from January 2023 to date August 20, 2024. 3. Review of Abbott Cell-Dyn Emerald 22 AL hematology analyzer quality control (QC) showed the laboratory could not provide documentation for QC performed each day of patient testing on the Abbott Cell-Dyn Emerald 22 AL hematology analyzer. 4. Interview with the TP #2 on August 20, 2024 at 10:00 AM confirmed the laboratory failed to document two control materials each day of patient testing.
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 observation of the laboratory, review of laboratory procedures, review of form CMS 209 provided by the laboratory, review of proficiency testing (PT) records, review of the Abbott Cell-Dyn Emerald 22 AL hematology analyzer quality control

	(QC), patient reports, review of chemistry QC and interviews, the laboratory director (LD) failed to provide overall management and direction to the laboratory. The laboratory director (LD) failed to provide overall operation of the laboratory (Refer to D6004); the LD failed to ensure PT samples are tested by all of the individuals who perform patient testing (Refer to D6016); the LD failed to ensure all proficiency testing reports received were reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action (Refer to D6018); the LD failed to ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory (Refer to D6019); the LD failed to ensure that the quality control program is maintained to identify failures in quality as they occur (Refer to D6022); and the LD failed to ensure the establishment and maintenance of acceptable levels of analytical performance for chemistry (Refer to D6023).
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on observation of laboratory and interview with the laboratory director, the laboratory director failed to provide overall operation of the laboratory. Findings: 1. Observation of laboratory revealed 12 urines in sink with patient names only, no collection dates, no documented time of collection and no date of births. 2. Observation of laboratory revealed expired materials (refer to D5417). 3. Observation of laboratory revealed patient reports in boxes and piled around the laboratory with patient ID numbers that the laboratory could not show matching patient reports in the LIS. 4. Observation of laboratory revealed the Abbott Cell-Dyn Emerald 22 AL hematology analyzer still in use with patient reports mixed with other documentation on shelf above analyzer, in boxes below analyzer, in piles beside analyzer, and no space to process biohazardous samples. The Olympus AU400 chemistry analyzer and Access 2 chemistry analyzer were no longer in use but expired supplies were piled all around analyzers. Overall the laboratory was a messy environment and very disorganized. 5. Interview with the laboratory director on August 20, 2024 at 11:00 AM confirmed the laboratory director failed to provide overall operation of the laboratory.
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 review of laboratory procedures, form CMS 209 provided by the laboratory, proficiency testing (PT) records from 2023 and to date August 20, 2024 and interview with testing personnel (TP) # 2, the laboratory director failed to ensure PT samples are tested by all of the individuals who perform patient testing. Findings: 1. Review of the laboratory procedure "Proficiency Testing" states "Testing of proficiency samples should be rotated among all laboratory staff performing patient testing." 2. Review of form CMS 209 provided by the laboratory showed the laboratory has three testing personal (TP). 3. Review of 2023 and to date August 20, 2024 proficiency testing (PT) records showed that TP #2 performed 5 of 5 PT testing events. 4. Interview with testing personnel #2 on August 20, 2024 at 10:00 AM confirmed all of the PT samples for 2023 and to date August 20, 2024 were performed by TP #2.
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 review of the 2023 and to date August 20, 2024 proficiency testing (PT) records and interview with the testing personnel (TP) #2, the laboratory director failed to ensure all proficiency testing reports received were reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. Findings: 1. Review of the 2023 chemistry core first, second and third proficiency testing events and the 2024 chemistry core first proficiency testing event showed the laboratory obtained a "Not Graded" result for all samples for the analyte bilirubin, direct. The laboratory could not provide documentation to show appropriate staff evaluated the "Not Graded" results to identify any problems that may require corrective action. 2. Interview with TP #2 on August 20, 2024 at 10:00 AM confirmed, the laboratory director failed to ensure all proficiency testing reports received were reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.
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 proficiency testing (PT) records for 2023, interview with the testing personnel (TP) #2, the laboratory director failed to ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory. Findings: 1. Review of the 2023 Chemistry Core first event PT record showed no corrective action plan for the following unacceptable results: CH-01 phosphorus GLY- 01 and GLY-02 glycated hemoglobin (%) 2. Interview with the TP #2 on August 20, 2024 at 10:30 AM confirmed the laboratory director failed to ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory.
D6022	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 and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of laboratory procedures, review of the Abbott Cell-Dyn Emerald 22 AL hematology analyzer quality control (QC), patient reports and interview with the testing personnel (TP) #2, the laboratory director failed to ensure that the quality control program is maintained to identify failures in quality as they occur. Findings: 1. Review of laboratory procedure "Quality Control Materials" states, "Quality control materials must be performed on each day of use. Instruments that require 3 quality control, 2 out of 3 controls must pass before performing patient tests." 2. Review of QC for the Cell-Dyn Emerald 22 AL hematology analyzer showed on June 7, 2024 normal and high hematology QC was unacceptable. 3. Review of patient reports showed patient 060720241 was performed when QC was unacceptable. The laboratory was unable to provide the total number of patients tests performed while QC was unacceptable. 4. Interview with the testing personnel (TP) #2 on August 20, 2024 at 10:30 AM confirmed the laboratory director failed to ensure that the quality control program is maintained to identify failures in quality as they occur.
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) 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)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by: Based on review of chemistry procedures, chemistry quality control (QC) and

	interview with the lab director (LD), the lab director failed to ensure the establishment and maintenance of acceptable levels of analytical performance for chemistry. Findings: 1. Review of the "Quality Control Materials" procedure states "Instruments that require 3 quality control, 2 out of 3 controls must pass before performing patient tests.". 2. Review of February 2024 Olympus AU400 chemistry analyzer QC showed on February 20, 2024 and February 22, 2024 Alkaline phosphatase level 1 and level 2 were not within acceptable limits. 3. Review of March 2023 Access 2 chemistry analyzer QC showed on March 9, 2023 prostate stimulating hormone level 1, level 2 and level 3 were not within acceptable limits. 4. Review of May 2023 Access 2 chemistry analyzer QC showed on May 4, 2023 free T4 level 2 and level 3 were not within acceptable limits. On May 16, 2023 free T4 level 1 and level 2 were not within acceptable limits. 5. The laboratory could not provide patient numbers for the days QC was not within acceptable limits. 6. Interview with the LD on August 20, 2024 at 11:00 AM confirmed the LD failed to ensure acceptable levels of analytical performance for chemistry.