Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D1025536	10/01/2025
Name of Provider or Supplier	**Street Address, City, State**	
Sunrise Clinical Laboratory Inc	21216 Olean Blvd Ste 3, Port Charlotte, FL	

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

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	An announced CLIA recertification survey was conducted at Sunrise Clinical Laboratory Inc on 09/22/2025 through 10/01/2025. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Conditions were cited: D2016 493.803 Condition: Successful Participation D5200 493. 1230 Condition: General Laboratory Systems D5400 493.1250 Condition: Analytic Systems D6000 493.1403 Condition: Moderate Complexity Laboratory Director
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on the review of the the laboratory's American Proficiency Institute (API) proficiency testing records and interview, the laboratory did not have successful

	participation in proficiency testing for the subspecialty of routine chemistry. (See D2097)
D2097	ROUTINE CHEMISTRY CFR(s): 493.841(g) (g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on the review of the the laboratory's American Proficiency Institute (API) proficiency testing records and interview, the laboratory did not have successful participation in proficiency testing for the subspecialty of routine chemistry. Findings included: 1. The API 2024 Chemistry-Core 1st event Performance Summary documented the laboratory had received a score of 20% for the 2023 3rd event and 60% for the 2024 1st event for TIBC (Total Iron Binding Capacity). The API 2024 Chemistry-Core 1st event Performance Summary documented "Unsuccessful". 2. Testing Personnel A (TP-A) confirmed on 9/22/2025 at 2:10 p.m., the above unsuccessful participation of the laboratory for TIBC. The Laboratory Director on 9/23 /2025 at 2:10 p.m. confirmed the documentation by API of "Unsuccessful" for the performance of TIBC due to two in a row unsatisfactory scores.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. In addition, retain the following: This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to maintain analytic records for 6/2024, 3/2025, and 7/2025 for the speciality of Immunology (Rheumatoid Factor-RF) testing. Findings included: 1. Review of Rheumatoid Factor-RF quality control (QC) records for 6/2024, 3/2025, and 7/2025 showed QC performance and lot numbers and expiration dates of reagents. There were no patient electronic or paper log of analytic performance of patient testing for RF for the days documented on the QC records for 6/2024, 3/2025, and 7/2025. 2. Testing Personnel A (TP-A) stated on 9 /23/25 at 9:35 a.m., patient results were entered directly into the Laboratory Information System (LIS) and that record of the patient analytic performance was not retained, only the quality control records. 3. The Laboratory Director on 9/23/2025 at 2:10 p.m. indicated he thought the laboratory kept sufficient records of the RF testing.
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, 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 general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on record review, review of the 2023 accepted Allegation of Compliance, and interviews, the laboratory failed to verify the accuracy of analytes not evaluated or scored by the proficiency testing program used by the laboratory, American Proficiency Institute (API), from 3rd event of 2023 to 2nd event of 2025 (D5215) and the laboratory failed to identify and take documented corrective actions for proficiency scores less than 100% from the 3rd event of 2023 to the 2nd event of 2025 for the specialities of Hematology and Chemistry. This is a repeat deficient deficiency from the 10/10/2023 recertification survey. (See D5221).
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to verify the accuracy of analytes not evaluated or scored by the proficiency testing program used by the laboratory, American Proficiency Institute (API), from 3rd event of 2023 to 2nd event of 2025. Findings included: 1. The API proficiency Testing Performance Evaluation report stated "Laboratories should review the Performance Summary and Comparative Evaluation thoroughly for failures and "not graded" analytes. Laboratories are responsible for documenting and performing corrective action for failures and must perform a self-evaluation using statistics presented in the Participant Data Summary for samples that have not been graded." 2. The following API scores were documented as "Not Graded" 2023 3rd event Hematology for Lymphocytes DXH-11 and DXH-14, DIF-03 for Lymphocyte (Diff), Monocyte (Diff), Neutrophil (Diff), and Neutrophil, segmented (Diff). 2024 1st event Hematology for DIF-01 for Lymphocyte (Diff), Monocyte (Diff), Neutrophil (Diff), and Neutrophil, segmented (Diff), and ECI-01, ECI-02, ECI-03, ECI-04, and ECI-05 for Blood Cell Identification. 2024 2nd event Hematology for DIF-02 for Lymphocyte (Diff), Monocyte (Diff), Neutrophil (Diff), and Neutrophil, segmented (Diff), Platelet Estimate (Diff), RBC (Red Blood Cell) Morphology (Diff), and ECI-06, ECI-07, and ECI-10 Blood Cell ID (Identification). 2024 3rd event Hematology for DIF-03 for Basophil (Diff), Eosinophils (Diff), Lymphocyte (Diff), Monocyte (Diff), Neutrophil (Diff), and Neutrophil, segmented (Diff), Platelet Estimate (Diff), and ECI-11, ECI-12, ECI-13, ECI-14, and ECI-15 Blood Cell ID (Identification). 2025 1st event Hematology for DIF-01 Platelet Estimate (Diff), and RBC (Red Blood Cell) Morphology (Diff), and ECI-01, ECI-02, ECI-03, ECI-04, and ECI-05 Blood Cell ID (Identification). 2025 2nd event Hematology for DIF-02 for Eosinophils (Diff), Lymphocyte (Diff), Lymphocyte, reactive (Diff), Monocyte (Diff), Neutrophil (Diff), and Neutrophil, segmented (Diff), Platelet Estimate (Diff), and ECI-02, ECI-07, ECI-08, ECI-09, and ECI-10 Blood Cell ID (Identification). 2024 1st event Chemistry-Core for CH-01, CH-02, and CH-05 for Bilirubin, Total and CH-01, CH-02, CH-03, CH-04 and CH-05 for

	TIBC (Total Iron Binding Capacity). 2024 2nd event Chemistry-Core for CH-08 for Iron, Total. 2025 2nd event Chemistry-Core for CH-07, CH-09, and CH-10 for Bilirubin, Total, CH-06, CH-07, CH-08, CH-9 and CH-10 for TIBC (Total Iron Binding Capacity), and for IA-07 and IA-09 for Folate. 3. There was no documentation of the laboratory performing a self-evaluation using statistics presented in the Participant Data Summary for samples that have not been graded." as stated in the API guidance. 4. Testing Personnel A confirmed on 9/22/2025 at 2:10 p. m., the laboratory did not perform or document a self-evaluation of ungraded scores received from API. 5. The Laboratory Director stated on 9/23/2025 at 2:10 p.m., he was not aware that ungraded scores were to be self-evaluated with documentation.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on record review, review of the 2023 accepted Allegation of Compliance, and interviews, the laboratory failed to identify and take documented corrective actions for proficiency scores less than 100% from the 3rd event of 2023 to the 2nd event of 2025 for the specialities of Hematology and Chemistry. This is a repeat deficient deficiency from the 10/10/2023 recertification survey. Findings included: 1. The American Proficiency Institute (API) proficiency Testing Performance Evaluation report stated "Laboratories should review the Performance Summary and Comparative Evaluation thoroughly for failures... Laboratories are responsible for documenting and performing corrective action for failures" 2. The Allegation of Compliance Plan signed by the Laboratory Director 11/28/2023 for the recertification survey performed 10/10/2023 showed for D5221 "the Medical Director (the Laboratory Director) review and corrective action will be taken on any failed results. In the future will evaluate any results that don't pass at a 100%." 3. The Procedure titled Proficiency Testing reviewed and signed by the Laboratory Director 1/2/2024 and 1/2/2025 showed under #7, when there is an unsatisfactory performance on any testing event,, the appropriate section shall undertake appropriate training and take action to correct the problems associated with the unsatisfactory event. Under Responsibilities it states it is the responsibility of the Laboratory Director and supervisor (who is also the Laboratory Director) to ensure that this guideline is followed. 4. The following API scores of less 100% received by the laboratory without corrective actions taken, including training: Hematology For 2023 3rd event the laboratory received scores for MCH (Mean Corpuscular Hemoglobin) 40% and for RDW (Red Cell Distribution Width) 0%, there was no documentation of corrective action taken or training needs identified or performed specific for each analyte. The review of this event was documented by the Laboratory Director on 1/17/2024. For 2025 1st event the laboratory received scores for Hematocrit (HCT) and Hemoglobin of 80%, there was no documentation of corrective action taken or training needs identified or performed specific for each analyte. The review of this event was documented by the Laboratory Director on 4/30 /2025 For 2025 2nd event for MCHC (Mean Corpuscular Hemoglobin Concentration) and Eosinophils of 80%, there was no documentation of corrective action taken or training needs identified or performed specific for each analyte. The review of this event was documented by the Laboratory Director on 8/18/2025 with the statement "all results acceptable". Chemistry For 2024 1st event the laboratory received scores for T-Uptake, Testosterone, LDL Cholesterol, and Free T3 of 80%, there was no documentation of corrective action taken or training needs identified or performed

	specific for each analyte. The review of this event was documented by the Laboratory Director on 3/23/2025 and 2/28/2024. For 2024 2nd event the laboratory received scores for Bilirubin, Total of 60%, there was no documentation of corrective action taken or training needs identified or performed specific for each analyte. The review of this event was documented by the Laboratory Director on 7/03/2024. For 2024 3rd event the laboratory received scores for CO2 (Carbon Dioxide) of 60% and Urea Nitrogen of 80%, there was no documentation of corrective action taken or training needs identified or performed specific for each analyte. The review of this event was documented by the Laboratory Director on 10/08/2024. For 2025 2nd event the laboratory received scores for Free T3 of 60% and 25-OH Vitamin D of 50%, there was no documentation of corrective action taken or training needs identified or performed specific for each analyte other than repeating the samples. The review of this event was documented by the Laboratory Director on 6/24/2025. 5. Testing Personnel A confirmed on 9/22/2025 at 2:10 p.m., the laboratory had not clearly identified which analytes had scores of less than 100% and had not documented taking specific corrective actions to ensure good testing performance. 6. The Laboratory Director stated on 9/23/2025 at 2:10 p.m., he reviewed each API event evaluations but could not explain the lack of effective corrective actions as indicated in the laboratory procedure and accepted Allegation of Compliance signed 11/28/2023 by him.
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, record review, review of the allegation of compliance from the 10/10/2023 recertification survey, and staff interviews, the laboratory (1) failed to verify the accuracy for the analytes tested on the Beckman Coulter Access 2 analyzer prior to reporting patient test results on 11/13/2024 for the subspecialties of Routine Chemistry and Endocrinology and failed to verify the accuracy, precision and reportable range for the analytes tested on the Beckman Coulter AU480 prior to reporting patient test results on 10/24/2024 for the subspecialties of Routine Chemistry and Urinalysis, see D5421, (2) failed to perform yearly maintenance for the Sysmex CA-500 instrument from 12/2023 through 08/2025 (21 months) per the manufacturer instructions for the speciality of Hematology for the tests PT-INR (International Normalized Ratio of the Prothrombin Time), see D5429, (3) failed to establish a procedure for performing function checks on five pipettes used peripherally for patient testing from 12/2023 to 9/2025, see D5431, (4) failed to perform monthly calibrations for the Sysmex CA-500 instrument from 01/2024 through 08/2025 (20 months) per the manufacturer instructions for the speciality of Hematology for the tests PT-INR (International Normalized Ratio of the Prothrombin Time), see D5437, (5) failed to perform and document calibration verification at least once every 6 months for speciality of Chemistry performed on the AU480 analyzer from 10/24/2024 to 8/18/2025, see D5439, (6) failed to establish a policy to monitor over time, the accuracy and precision of controls, and for maintaining documentation

	of monitoring, for the specialty of Hematology from 12/2023 through 08/2025 (21 months). This is a repeat citation, see D5441, (7) failed to perform new lot verifications (verify controls were within acceptable parameters prior to placing them into use) for the subspecialties of General Immunology, Routine Chemistry, Urinalysis, Endocrinology and the specialty of Hematology from 12/2023 through 09 /2025 (22 months), see D5469, (8) failed to enter the International Sensitivity Index (ISI) correction factor, failed to perform and enter the mean normal range for PT (Prothrombin Time) when changing any reagent or control lots for the Sysmex CA-500 instrument for the specialty of Hematology for the test PT-INR (International Normalized Ratio of the Prothrombin Time) from 12/2023 - 08/2025 (21 months), see D5545, and (9) failed to follow it's policy of monitoring accessing, and identifying problems for the analytic system from 12/2023 through 08/2025. This is a repeat deficiency, see D5791.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i) (A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to (1) verify the accuracy for the analytes tested on the Beckman Coulter Access 2 analyzer prior to reporting patient test results on 11/13/2024 for the subspecialties of Routine Chemistry and Endocrinology and (2) failed to verify the accuracy, precision, and reportable range for the analytes tested on the Beckman Coulter AU480 prior to reporting patient test results on 10/24/2024 for the subspecialties of Routine Chemistry and Urinalysis. Findings included: 1. The Access 2 analyzer verification binder was reviewed for the analytes vitamin D, prostate specific antigen, testosterone, free Triiodothyronine, free thyroxine, thyroid stimulating hormone, vitamin B12, and Folate. There was no documentation of verification of accuracy for these analytes. 1a. The Quality Assurance Review form for November 2024, signed by the Laboratory Director on 12 /03/2025 documented patient testing for the Access 2 analyzer started 11/14/2024. 2. The Beckman Coulter AU480 analyzer verification binder was reviewed for the analytes glucose, blood urea nitrogen, creatinine, sodium, potassium, chloride, carbon dioxide, calcium, total protein, albumin, alkaline phosphatase, aspartate aminotransferase, alanine aminotransferase, total bilirubin, cholesterol, Triglycerides, high density lipoprotein, low density lipoprotein, direct bilirubin, creatine kinase, iron, unsaturated iron binding capacity, magnesium, phosphorous, uric acid, hemoglobin A1C, urine albumin, urine creatinine, and urine protein. There were no documents, signed by the Laboratory Director to reflect the accuracy, precision or reportable range were reviewed and approved. 2a. The Quality Assurance Review form for October 2024, signed by the Laboratory Director on 11/07/2024 documented patient testing for the AU480 analyzer started on 10/24/2024. 3. The Laboratory Director was interviewed on 09/23/2025 at 1:45 p.m. He confirmed the above. He stated he signed what was presented to him by the person conducting the verification studies. When asked if he knew what was required prior to reporting patient results when a new

	analyzer or analytes were put into use, the Laboratory Director stated he was not aware of all the requirements.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) 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 record review and staff interview, the laboratory failed to perform yearly maintenance for the Sysmex CA-500 instrument from 12/2023 through 08/2025 (21 months) per the manufacturer instructions for the speciality of Hematology for the tests PT-INR (International Normalized Ratio of the Prothrombin Time). Findings included: 1. The Sysmex CA-500 series automated blood coagulation analyzer manufacturer manual, with a revision date of April 2004 was reviewed. Page 11-1 stated the rinse filter must be replaced yearly. 2. The Sysmex CA-500 Maintenance Checklist for 06/2024, 03/2025, and 07/2025 were reviewed. The forms were signed by the laboratory director on 6/12/2025, 04/04/2025, and 08/18/2025 respectively. Each form had a section to document yearly replacement of the rinse water line filter. No form documented a filter change. 3. Yearly maintenance, specifically replacing the rinse water line filter were requested for dates of service 12/2023 through 08/2025. No records were available. 4. An interview was conducted with testing personnel #A on 09/22/2025 at 2:15 p.m. They stated they were unaware the rinse water line filter had to be replaced yearly and the laboratory had not completed filter replacements. 5. An interview was conducted with the laboratory director on 09/23/2025 at 1:45 p.m. He stated he was not involved in the minutia of the laboratory and was not aware of all the requirements.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) (a)(2) Function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturers established limits before patient testing is conducted. (b) 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 do the following: This STANDARD is not met as evidenced by: Based on observation, record review, and interview, it was determined the laboratory failed to have an established procedure for performing function checks on five pipettes used peripherally for patient testing from 12/2023 to 09/2025. Findings included: 1. Five pipettes were observed on 09/22/25 at 10:05 a.m. for use in the laboratory. The five pipettes did not have stickers indicating verification of function checks for accuracy. 2. Quality Control Certificates for pipettes in use documented the oldest date was 12/19/2023 and the most current was 07/17/2024. There was no procedure or documentation that the five pipettes used by the laboratory had been verified for accuracy since put into use. 3. Testing Personnel A confirmed on 09/23 /2025 at 10:30 a.m. the laboratory did not have a procedure or process for verification of function checks for accuracy of the pipettes in use. 4. The Laboratory Director

	stated on 09/23/2025 at 2:10 p.m. he thought the pipettes were checked by the laboratory staff.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) (a)Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (a)(1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (a)(2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (a)(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 (a)(2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (a)(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 record review and staff interview, the laboratory failed to perform monthly calibrations for the Sysmex CA-500 instrument from 01/2024 through 08/2025 (20 months) per the manufacturer instructions for the speciality of Hematology for the tests PT-INR (International Normalized Ratio of the Prothrombin Time). Findings included: 1. The Sysmex CA-500 series automated blood coagulation analyzer manufacturer manual, with a revision date of April 2004 was reviewed. Page 11-1 stated the LED lamp was to be calibrated monthly. 2. The Sysmex CA-500 Maintenance Checklist for 06/2024, 03/2025, and 07/2025 were reviewed. The forms were signed by the laboratory director on 6/12/2025, 04/04/2025, and 08/18/2025 respectively. Each form had a section to document quarterly LED lamp calibrations. No form documented a calibration. 3. Calibration records were requested for dates of service 01/2024 through 08/2025. No calibration records were available. 4. An interview was conducted with testing personnel #A on 09/22/2025 at 2:15 p.m. They stated they were unaware LED lamp calibrations were required monthly and that the laboratory had not performed any calibrations. 5. An interview was conducted with the Laboratory Director on 09/23/2025 at 1:45 p.m. He stated he was not involved in the minutia of the laboratory and was not aware of all the requirements.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (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 record review and interviews, it was determined the laboratory failed to perform and document calibration verification at least once every 6 months for the speciality of Chemistry performed on the AU480 analyzer from 10/24/2024 to 8/18 /2025. Findings included: 1. Linearity/Calibration Verification reports for the AU480 analyzer used for the speciality of Chemistry available for review were dated 8/18 /2025 and 8/19/2025. The date of initial installation of the AU480 was 10/24/2024. There was no documentation of 10/24/2024 to 8/18/2025. 2. Interview with Testing Personnel #A on 09/23/2025 at 11:30 a.m. and the Lab Director at 1:45 p.m. confirmed the above.
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. This STANDARD is not met as evidenced by: Based on record review, review of previous allegation of compliance, and staff interview, the laboratory failed to establish a policy to monitor over time, the accuracy and precision of controls, and maintaining documentation of monitoring for the specialty of Hematology from 12/2023 through 08/2025 (21 months). This is a repeat citation from the 10/10/2023 recertification survey. Finding included: 1. The allegation of compliance for the previous recertification survey conducted 10/10/2023, signed by the Laboratory Director on 11/28/2023, was reviewed. The plan stated, "Levy Jennings will be printed out monthly & reviewed for shifts & trends. Will be signed off & reviewed by the Laboratory Director monthly. The plan indicated the laboratory would comply effective 11/8/2023. 2. A policy and procedure and records were requested documenting the monitoring of controls for the Sysmex CA-500 and the Beckman Coulter DxH520 analyzer (both Hematology analyzers), such as Levy Jennings graphs, for 07/2025, 03/2025, and 06/2024. No policy and procedure nor documentation of monitoring the accuracy and precision of controls over time were available. 3. Interview with Testing Person #A on 09/23/2025 at 11:30 a.m., confirmed the laboratory had no policy for monitoring the accuracy and precision of quality controls over time for Hematology and no policy to document monitoring quality control over time. The laboratory had no documentation from 12/2023 through 08/2025.
D5469	CONTROL PROCEDURES

	CFR(s): 493.1256(d)(10)(g) (d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (d)(10)(ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (d)(10)(iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to perform new lot verifications (verify controls were within acceptable parameters prior to placing them into use) for the subspecialties of General Immunology, Routine Chemistry, Urinalysis, Endocrinology and the specialty of Hematology from 12/2023 through 09/2025 (22 months). Findings included: 1. The policy and procedure for new lot verifications of quality control materials and documentation of new lot verification for all analytes were requested for the analytes; prothrombin time, INR (international normalization ratio), white blood cell count, red blood cell count, platelets, hemoglobin, vitamin D, prostate specific antigen, testosterone, free Triiodothyronine, free thyroxine, thyroid stimulating hormone, vitamin B12, Folate, glucose, blood urea nitrogen, creatinine, sodium, potassium, chloride, carbon dioxide, calcium, total protein, albumin, alkaline phosphatase, aspartate aminotransferase, alanine aminotransferase, total bilirubin, cholesterol, Triglycerides, high density lipoprotein, low density lipoprotein, direct bilirubin, creatine kinase, iron, unsaturated iron binding capacity, magnesium, phosphorous, uric acid, hemoglobin A1C, urine albumin, urine creatinine, and urine protein. No policy and procedure was available and no new lot verifications were present from 12/2023 through 09/2025. 2. Testing person #A was interviewed on 09/23/2025 at 10:30 a.m. They confirmed the above, the laboratory did not have a policy to verify new lots of quality controls for any of the analytes tested prior to putting them into use and was not verifying new lots of quality control prior to use.
D5545	HEMATOLOGY CFR(s): 493.1269(b)(d) (b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to enter the International Sensitivity Index (ISI) correction factor, and failed to perform and enter the mean normal range for PT (Prothrombin Time) when changing any reagent or control lots for the Sysmex CA-500 instrument for the specialty of Hematology for the test PT-INR (International Normalized Ratio of the Prothrombin Time) from 12/2023 - 08/2025 (21 months). Findings included: 1. A laboratory policy and procedure was requested regarding verifying the mean normal range for PT or input the mean normal range for PT or ISI correction factor when reagent lots were changed. 2. Records were requested for any and all documentation of reagent changes, mean

	normal range for PT determinations, input of the value as well as the ISI into the analyzer when reagents were changed from 12/2023 through 08/2025. No documents were available. 3. An interview was conducted with testing personnel #A (TP #A) on 09/22/2025 at 2:15 p.m. They stated they were unaware establishing the mean normal range for PT and entering it and the ISI correction factor into the coagulation analyzer were required. TP #A said the laboratory did not keep a physical reagent change log. The laboratory did not have a policy to verify the mean normal PT or the input of that mean or the ISI correction factor when reagents were changed. TP #A said the laboratory had not performed any of the above. 5. An interview was conducted with the Laboratory Director on 09/23/2025 at 1:45 p.m. He stated he was not involved in the minutia of the lab and was not aware of all the requirements.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. This STANDARD is not met as evidenced by: Based on record review, review of the laboratory's allegation of compliance from the 10/10/2023 survey, and staff interview, the laboratory failed to follow it's policy of monitoring accessing, and identifying problems for the analytic system from 12/2023 through 08/2025. This is a repeat deficiency from the 10/10/2023 recertification survey. Findings included: 1. The allegation of compliance from the 10/10/2023 recertification survey, signed by the Laboratory Director 11/28/2023, was reviewed. The plan indicated a policy was created to ensure the analytic phase of testing was reviewed and a quality assurance checklist would be signed off by the director to ensure ongoing compliance. The plan indicated the laboratory would comply with this requirement by 11/8/2023. 2. The Quality Assurance policy, signed by the Laboratory Director 11/01/2023 stated the laboratory would ensure quality throughout the analytic phase of testing. The policy stated quality controls would be reviewed on-going, looking for drifts, shifts and/or any indication of analytical problems and calibration procedures for each method or instrument would be followed per the method or instrument manufacturer's directions. 3. The laboratory's Quality Assurance Review for 11/2023 through 08/2023 were reviewed. The form was not a checklist as stated in the plan of correction. The forms for each month were signed by the Laboratory Director as follows; November 2023 - 12/15/2023, December 2024 - 01/10 /2024, January 2024 - 02/05/2024, February 2024 - 03/11/2024, March 2024 - 04/09 /2024, April 2024 - 05/10/2024, May 2024 - 06/03/2024, June 2024 - 07/09/2024, July 2024 - 08/07/2024, August 2024 - 09/09/2024, September 2024 - 10/02/2024, October 2024 - 11/07/2024, November 2024 - 12/03/2024, December 2024 - 01/06/2025, January 2025 - 02/10/2025, February 2025 - 03/14/2025, March 2025 - 04/30/2025, April 2025 - 05/09/2025, May 2025 - 06/03/2025, June 2025 - 07/08/2025, July 2025 - 08/05/2025, and August 2025 - 09/15/2025. There were no analytic problems identified on any of the forms. See D5421, D5429, D5431, D5437, D5489, D5441, D5469, and D5545 regarding noncompliance identified for analytic systems. 4. The Laboratory Director was interviewed 09/23/2025 at 1:45 p.m. He stated he was not involved in the minutia of the laboratory and did not know all of the requirements.
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 record review, review of the Allegation of Compliance/Plan of Correction from the 10/10/2023 recertification survey, and staff interviews, the Laboratory Director failed to provide effective overall management and direction of the laboratory. Findings Included: 1. The Laboratory Director failed to establish a policy to document they were onsite every 6 months to include evidence of performing Laboratory Director responsibilities. See D6005. 2. The Laboratory Director failed to ensure (1) the accuracy for the analytes tested on the Beckman Coulter Access 2 analyzer were verified prior to reporting patient test results on 11/13/2024 for the subspecialties of Routine Chemistry and Endocrinology and (2) failed to ensure the accuracy, precision and reportable range for the analytes tested on the Beckman Coulter AU480 were verified prior to reporting patient test results on 10/24/2024 for the subspecialties of Routine Chemistry and Urinalysis. See D6013. 3. The Laboratory Director failed to evaluate the laboratory's proficiency testing performance to identify problems that might require action. See D6018. 4. The Laboratory Director failed to ensure the laboratory followed it's policy of monitoring accessing, and identifying problems for the analytic system to assure the quality of the testing performed from 12/2023 through 08/2025. See D6020. 5. The Laboratory Director failed to ensure testing personnel were appropriately trained on how to enter the International Sensitivity Index (ISI) correction factor, and how to perform the mean normal range for PT (Prothrombin Time) when changing any reagent or control lots for the Sysmex CA-500 instrument for the specialty of Hematology, for the test PT-INR (International Normalized Ratio of the Prothrombin Time). Testing was performed from 12/2023 - 08/2025 (21 months). See D6029.
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, record review, review of the 2023 Allegation of Compliance, and staff interview, the Laboratory Director failed to provide effective oversight and administration of the laboratory from 12/2023 through 09/2025. Findings included: 1. The Laboratory Director failed to establish a policy to document they were onsite every 6 months to include evidence of performing laboratory director responsibilities. See D6005. 2. The Laboratory Director failed to ensure (1) the accuracy for the analytes tested on the Beckman Coulter Access 2 analyzer were verified prior to

	reporting patient test results on 11/13/2024 for the subspecialties of Routine Chemistry and Endocrinology and (2) failed to ensure the accuracy, precision and reportable range for the analytes tested on the Beckman Coulter AU480 were verified prior to reporting patient test results on 10/24/2024 for the subspecialties of Routine Chemistry and Urinalysis. See D6013. 3. The Laboratory Director failed to evaluate the laboratory's proficiency testing performance to identify problems that may require action. See D6018. 4. The Laboratory Director failed to ensure the laboratory followed it's policy of monitoring accessing, and identifying problems for the analytic system to assure the quality of the testing performed from 12/2023 through 08/2025. See D6020. 5. The Laboratory Director failed to ensure testing personnel were appropriately trained on how to enter the International Sensitivity Index (ISI) correction factor, and how to perform the mean normal range for PT (Prothrombin Time) when changing any reagent or control lots for the Sysmex CA-500 instrument for the specialty of Hematology, for the test PT-INR (International Normalized Ratio of the Prothrombin Time). Testing was performed from 12/2023 - 08/2025 (21 months). See D6029. 6. The Laboratory Director failed to ensure analytic records for 6 /2024, 3/2025, and 7/2025 for the specialty of Immunology (Rheumatoid Factor - RF) testing were retained. See D3031.
D6005	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(c) (c) The laboratory director must: (c)(1) Be onsite at least once every 6 months, with at least 4 months between the minimum two on-site visits. Laboratory directors may elect to be on-site more frequently and must continue to be accessible to the laboratory to provide telephone or electronic consultation as needed; and (c)(2) Provide documentation of these visits, including evidence of performing activities that are part of the laboratory director responsibilities. This STANDARD is not met as evidenced by: Based on record review and staff interview, the Laboratory Director failed to establish a policy to document he was onsite every 6 months to include evidence of performing Laboratory Director responsibilities. Finding included: 1. The laboratory policy and procedure manual, signed by the Laboratory Director 01/02/2025 was reviewed. No policy was present to document the Laboratory Director was onsite every 6 months to include evidence of performing Laboratory Director responsibilities. 2. The Laboratory Director was interviewed on 09/23/2025 at 1:45 p.m. He confirmed no policy was established and stated he was not concerned as he was onsite every few weeks.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to ensure (1) the accuracy for the analytes tested on the Beckman Coulter Access 2 analyzer were verified prior to reporting patient test results on 11/13/2024 for the subspecialties of Routine Chemistry and Endocrinology and (2) failed to ensure the accuracy, precision

	and reportable range for the analytes tested on the Beckman Coulter AU480 were verified prior to reporting patient test results on 10/24/2024 for the subspecialties of Routine Chemistry and Urinalysis. Findings included: 1. The Access 2 analyzer verification binder was reviewed for the analytes vitamin D, prostate specific antigen, testosterone, free Triiodothyronine, free thyroxine, thyroid stimulating hormone, vitamin B12, and Folate. There was no documentation of verification of accuracy for these analytes. 1a. The Quality Assurance Review form for November 2024, signed by the Laboratory Director on 12/03/2025 documented patient testing for the Access 2 analyzer started 11/14/2024. 2. The Beckman Coulter AU480 analyzer verification binder was reviewed for the analytes glucose, blood urea nitrogen, creatinine, sodium, potassium, chloride, carbon dioxide, calcium, total protein, albumin, alkaline phosphatase, aspartate aminotransferase, alanine aminotransferase, total bilirubin, cholesterol, Triglycerides, high density lipoprotein, low density lipoprotein, direct bilirubin, creatine kinase, iron, unsaturated iron binding capacity, magnesium, phosphorous, uric acid, hemoglobin A1C, urine albumin, urine creatinine, and urine protein. There were no documents, signed by the Laboratory Director to reflect the accuracy, precision, or reportable range were reviewed and approved. 2a. The Quality Assurance Review form for October 2024, signed by the Laboratory Director on 11/07 /2024 documented patient testing for the AU480 analyzer started on 10/24/2024. 3. The Laboratory Director was interviewed on 09/23/2025 at 1:45 p.m. He confirmed the above. He stated he signed what was presented to him by the manufacturer representative who performed the verification studies. When asked if he knew what was required prior to reporting patient results when a new analyzer or analyte were put into use, the Laboratory Director stated he was not aware of the requirements.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) (e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratorys performance and to identify any problems that require corrective action; and This STANDARD is not met as evidenced by: Based on record review, review of the 2023 accepted Allegation of Compliance, and staff interviews, the Laboratory Director failed to evaluate the laboratory's proficiency testing performance to identify problems that might require action. Findings included: 1. The laboratory failed to verify the accuracy of analytes not evaluated or scored by the proficiency testing program used by the laboratory, American Proficiency Institute (API), from 3rd event of 2023 to 2nd event of 2025. See D2016. 2. The laboratory failed to identify and take documented corrective actions for proficiency scores less than 100% from the 3rd event of 2023 to the 2nd event of 2025 for the specialities of Hematology and Chemistry. This is a repeat deficiency from the 10/10/2023 recertification survey. See D5221.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;

	This STANDARD is not met as evidenced by: Based on record review, review of the laboratory's plan of correction from the 10/10 /2023 survey, and staff interview, the Laboratory Director failed to ensure the laboratory followed it's policy of monitoring, accessing, and identifying problems for the analytic system to assure the quality of the testing performed from 12/2023 through 08/2025. Findings included: 1. The allegation of compliance from the 10/10 /2023 recertification survey, signed by the Laboratory Director 11/28/2023 was reviewed. The plan indicated a policy was created to ensure the analytic phase of testing was reviewed and a quality assurance checklist would be signed off by the director to ensure ongoing compliance. The plan indicated the laboratory would comply with this requirement by 11/8/2023. 2. The Quality Assurance policy, signed by the Laboratory Director 11/01/2023 stated the laboratory would ensure quality throughout the analytic phase of testing. The policy stated quality controls would be reviewed on-going, looking for drifts, shifts, and/or any indication of analytical problems and calibration procedures for each method or instrument would be followed per the method or instrument manufacturer's directions. 3. The laboratory's Quality Assurance Review for 11/2023 through 08/2023 were reviewed. The form was not a checklist as stated in the plan of correction. The forms for each month were signed by the Laboratory Director as follows; November 2023 - 12/15/2023, December 2024 - 01/10/2024, January 2024 - 02/05/2024, February 2024 - 03/11 /2024, March 2024 - 04/09/2024, April 2024 - 05/10/2024, May 2024 - 06/03/2024, June 2024 - 07/09/2024, July 2024 - 08/07/2024, August 2024 - 09/09/2024, September 2024 - 10/02/2024, October 2024 - 11/07/2024, November 2024 - 12/03 /2024, December 2024 - 01/06/2025, January 2025 - 02/10/2025, February 2025 - 03 /14/2025, March 2025 - 04/30/2025, April 2025 - 05/09/2025, May 2025 - 06/03 /2025, June 2025 - 07/08/2025, July 2025 - 08/05/2025, and August 2025 - 09/15 /2025. There were no analytic problems identified on any of the forms. See D5421, D5429, D5431, D5437, D5489, D5441, D5469, and D5545 regarding noncompliance identified for analytic systems. 4. The Laboratory Director was interviewed 09/23 /2025 at 1:45 p.m. He stated he was not involved in the minutia of the laboratory and did not know all the requirements.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) (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 record review and staff interview, the Laboratory Director failed to ensure testing personnel were appropriately trained on how to enter the International Sensitivity Index (ISI) correction factor and how to perform the mean normal range for PT (Prothrombin Time) when changing any reagent or control lots for the Sysmex CA-500 instrument for the specialty of Hematology, for the test PT-INR (International Normalized Ratio of the Prothrombin Time). Testing was performed from 12/2023 - 08/2025 (21 months). Findings included: 1. A laboratory policy and procedure was requested regarding verifying the mean normal range for PT or input the mean normal range for PT or ISI correction factor when reagent lots were changed. 2. Records were requested for any and all documentation of reagent changes, mean normal range for PT determinations, input of the value, as well as the ISI into the analyzer when

	reagents were changed from 12/2023 through 08/2025. No documents were available. 3. An interview was conducted with testing personnel (TP) #A on 09/22/2025 at 2:15 p.m. They stated they were unaware establishing the mean normal range for PT and entering it and the ISI correction factor into the coagulation analyzer were required. TP #A said the laboratory did not keep a physical reagent change log, did not have a policy to verify the mean normal PT or the input of that mean or the ISI correction factor when reagents were changed. TP #A verified the laboratory had not performed any of the above. 5. TP #A's annual competencies were reviewed. The Laboratory Director signed annual competencies on 01/08/2024 and 01/10/2025 indicating TP #A was trained and competent to perform all test operations to provide accurate results. 6. An interview was conducted with the Laboratory Director on 09/23/2025 at 1:45 p.m. He stated he was not aware of all the requirements.