Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0950355	02/14/2023
Name of Provider or Supplier	**Street Address, City, State**	
Brookridge Internal Medicine Associates Pa	300 N Third Street, Longview, 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 found out of compliance with the CLIA regulations. The following conditions were not met: D5400 - 42 C.F.R. 493.1250 Condition: Analytic systems; D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director;
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on review of 2022 Chemistry Core proficiency testing records, policies and procedures and interview of facility personnel the laboratory failed to test proficiency samples in the same manner as it tests patient specimens in three of three testing events for 2022. NOTE: THIS IS A REPEAT DEFICIENCY FROM THE 03/2023 INSPECTION Findings included: 1. Review of The American Proficiency Institute (API) proficiency 2022 Chemistry Core testing records for found that the laboratory tested five of five proficiency specimens in duplicate for each of the three testing events. 2. Review of the laboratory's own written procedure titled Profieciency Testing (dated 3/15/2022) found:"Proficiency testing is done quarterly on all moeratoely complex devices. It is ran as a patient sample. This includes rerunning if the values come in as critical." 3. During interview of testing person one listed on the CMS report 209 Laboratory Personnel Report conducted February 13, 2023 at 1:53

	PM, she confirmed that the laboratory tested 5 of 5 proficiency specimens twice each and that patient specimens were not tested twice each. She went on to say that she "used the results of the first run to report to the proficiency testing agency as it was the freshest even though she runs them back to back."
D2123	HEMATOLOGY CFR(s): 493.851(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on review of proficiency testing records for 2022 and interview of facility personnel, the laboratory failed to participate in 1 of 3 proficiency testing events resulting in an overall score of 0% for the 2022 Hematology /Coagulation 3rd event. The findings include: 1. A review of the 2022 American Proficiency Institute (API) 2022 proficiency testing records found the laboratory failed to participate in the Hematology/ coagulation -3rd event and received a score of 0% for the following analytes: Erythrocyte Count Hematocrit Hemoglobin Leukocyte Count MCH MCHC MCV MPV Platelet Count White Blood Cell Differential Neut/Gran Lymphocytes 2. During interview of testing person one listed on the CMS report 209 Laboratory Personnel Report conducted February 13, 2022 at 1:43 PM, she confirmed that the laboratory failed to test specimens and submit results to the proficiency testing agency before the submission deadline. She went on to explain that the laboratory had implemented the use of a new Hematology analyzer and when she received notification to submit results, she realized the sample set was not acceptable for use with the new analyzer.
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. This STANDARD is not met as evidenced by: Review of laboratory records for 2022 manufacturer's instructions for use and interview of facility personnel found that the laboratory failed to retain instrument printouts for the QC Device function checks performed each day when using the Triage meter (Serial number 00082753) for testing patient specimens with the Quidel Triage Tox Screen, 94600 and BNP. NOTE: THIS IS A REPEAT DEFICIENCY FROM THE 03/2022 INSPECTION Findings included: 1. Review of laboratory records found that the laboratory documented passing results for the QC Device but did not retain instrument printouts. 2. Review of the Quidel Triage Tox Drug Screen,

	9460 instructions for use found under the heading Quality Control Considerations: "Performing Quidel Triage System Quality Control - QC Device Use the QC Device to ensure proper function of the Meter. Perform QC Device testing for the following conditions: Upon initial setup of the Meter. Each day of patient testing. When the meter has been transported or moved. Whenever there is uncertainty about the performance of the meter. Whenever required by your laboratory's quality control requirements." 3. During interview of testing person one on the CMS report 209 Laboratory Personnel Report conducted February 13, 2023 at 3:12 PM, she confirmed that she did not retain instrument printouts for the QC device when using the Triage meter for testing patient specimens.
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based upon review of 2022 proficiency testing records and interview of facility personnel the laboratory failed to retain proficiency testing records for one of three Chemistry Core testing events, and one of three Hematology testing events for a minimum of two years. The findings included: 1. Review of the 2022 American Proficiency Institute (API) proficiency testing records found the laboratory failed to retain records for a minimum of two years as follows: a. 2022 Chemistry Miscellaneous 1st event - The laboratory failed to retain attestation statements, original forms, and instrument printouts. b. 2022 Hematology/ Coag 1st event - The laboratory failed to retain the attestation statement. 2. During interview of testing person one on the CMS report 209 Laboratory Personnel Report conducted February 13, 2023 at 2:21 PM, she confirmed that the laboratory did not retain these records.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) proficiency testing records from 2022 and staff interview, the laboratory failed to review and evaluate proficiency testing results for one of three events for hematology. The findings included: 1. Review of API proficiency testing records from 2022 (3 testing events annually) found no documentation of review for the 2022 Hematology/ Coagulation 2nd Event. 2. During interview of testing person one listed on the CMS Report 209 Laboratory Personnel Report conducted February 13, 2023 at 2:04 PM, she confirmed that proficiency testing records for the event was not documented.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

	This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute proficiency testing records from 2022, quality assurance policy, patient test records, and interview with facility personnel, the laboratory failed to verify the accuracy of nine of nine analytes tested in 2022 using the Triage Tox Drug Screen 94600. The findings included: 1. Based on review of American Proficiency Institute (API) proficiency testing records for 2022, there was no record of participation in a proficiency testing program for Toxicology, or another means of assessing the quality of results at least twice each year. 2. Review of the laboratoryr's own policy titled Quality Assurance Policies and Procedures found: " General Quality Policies 1. Quality in the entire test system is of foremost importance to this lab/ office. 2. All lab personnel are trained and properly commensurate with their positions, duties and responsibilities. 3. The lab maintains a quality control program to assure continued precision and accuracy of lab results. 4. This laboratory participates in HCFA approved proficiency testing program for all non-waived analyst tested." 3. Review of patient testing records found the laboratory recorded testing 583 patient specimens for 5247 toxicology tests using the Triage Tox Drug Screen 94600 test without verifying the accuracy of results at least twice each year. 4. During interview of testing person one on the CMS report 209 Laboratory Personnel Report conducted February 13, 2023 at 2:35 PM she confirmed that she did not enroll in a proficiency testing program or have another means to verify the accuracy of results for the urine drug screen using the Triage Tox Drug Screen 94600.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of policies and procedures, proficiency testing records, quality assurance activities and interview of facility personnel, the laboratory failed to follow written policies and procedures to monitor, assess, and correct problems identified in general laboratory system requirements at 493.1231 through 493.1236 in 2022 and 2023. The findings included: The laboratory failed to retain instrument printouts for QC Device checks performed on the Triage Pro Meter. (See D 3031) The laboratory failed to retain proficiency testing records for a minimum of two years. (See D 3037) The laboratory failed to review and evaluate proficiency testing results for one of three Chemistry events. (See D5211) The laboratory failed to verify the accuracy of urine drug screen testing at least twice annually in 2022. (Refer to D5217)
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 a review of laboratory policy, laboratory quality control (QC) records, manufacturer method verification manual, laboratory verification studies, manufacturer's instructions, patient final reports, and confirmed in interviews, the laboratory failed to monitor and evaluate the overall quality of the analytic systems and correct identified problems for the specialties, and their subspecialties, of Chemistry and Hematology in 2022. The findings include: 1. The laboratory failed to perform QC for Vitamin D testing on the FastPack system every week of patient testing as outlined by the laboratory's Individualized Quality Control Plan (IQCP) for 4 out of 13 QC documentation reviewed in April, June, and December of 2022. (Refer to D 5401) 2. The laboratory failed to perform reference range verification on the Sysmex XN 330 before it was put in use for patient testing in December of 2022. (Refer to D5421) 3. The laboratory failed to have a quality control program in place to detect immediate errors and errors over time for eighteen analytes tested on the Vitros 350 chemistry analyzer using the performance verifier controls. (Refer to D5441 part I) 4. The laboratory failed to have a system in place to monitor QC for accuracy and precision over time for two of two tests, TSH and Vitamin D, performed on the Qualigen FastPack analyzer for 2022. (Refer to D5441 part II) 5. The laboratory failed to test negative and positive control material at least once per day patient samples were tested for the TOX Drug Screen,9460 panel on the Quidel Triage Pro analyzer for 12 of 13 days in December 2022. (Refer to D5449)
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a review of laboratory policy, laboratory quality control (QC) records, patient test results, and confirmed in interview, the laboratory failed to perform QC for Vitamin D testing on the FastPack system every week of patient testing as outlined by the laboratory's Individualized Quality Control Plan (IQCP) for 4 out of 13 QC documentation reviewed in April, June, and December of 2022. The findings include: 1. Review of the laboratory IQCP for Vitamin D had the following instructions regarding quality control: "At this point QC will be ran weekly when patient samples are ran or prn with new lot numbers, calibration or maintenance is performed." 2. Review of the laboratory Vitamin D Control Log, and patient results, for April, June, and December 2022 had the following four elapses in weekly QC and the 53 total patients tested within those elapses. April 2022: QC documented on 4/4/2022 with the next QC documentation on 4/12/2022; time elapsed, 8 days. Patients tested within the elapsed days: 11 4/11/2022: 11 4069 1892 1253 844 580 3853 216 1026 462 3116 4066 QC documented on 4/18/2022 with the next QC documentation on 4/27/2022; time elapsed, 9 days. Patients tested within the elapsed days: 21 4/25/2022: 10 4088 209 2992 1885 3216 3703 687 712 1175 2957 4/26/2022: 11 4103 3807 59 7114 2476 19 3793 4110 2600 174 4112 QC documented on 6/8/2022 with the next QC documentation on 6/21/2022; time elapsed, 13 days. Patients tested within the elapsed days: 10 6/15/22: 3 patients 250 2605 179 6/16/22: 6 patients 11 185 2463 289 266

	3490 6/17/22: 1 patient 728 QC documented on 12/7/2022 with the next QC documented on 12/19/2022; time elapsed, 12 days Patients tested within the elapsed days: 11 12/15/2022: 8 patients 2510 763 396 2605 1405 4009 561 4173 12/16/2022: 3 patients 104 891 3 3. In an interview on 2/13/2023 at 15:20, in the breakroom, testing person (TP) 1 stated that the laboratory was performing Vitamin D QC on every new box opened, not weekly as outlined by laboratory IQCP.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of a manufacturer method verification manual, laboratory verification studies, patient final reports, and confirmed in an interview, the laboratory failed to perform reference range verification on the Sysmex XN-330 before it was put in use for patient testing in December of 2022. The findings include: 1. Review of the "Sysmex Method Verification Manual", section 3 "Method Verification Protocols" had the following statement: "It is the customer's responsibility to perform additional studies, following the requirements of their accrediting agency. The following protocols are provided: Correlation Studies Sensitivity Study Reference Range Verification Stability Study Mixing Study" 2. Review of the patient final report had the following reference ranges listed in use by the laboratory: Analyte - Final patient report ranges WBC - 3.6 - 11 10E3/uL RBC - 4.27 - 5.49 10E6/uL Hgb - 12.9 - 16.1 g /dL Hct - 37.7 - 46.5 % Plt - 165.0 - 353.0 10E3/uL Surveyor queried for the reference range verification for the above ranges used on the final patient report, on 2/24/2023 at 10:00 hours, and none was provided. 3. In an interview on 2/14/2023 at 10:22 in the laboratory, TP1 confirmed that the patient reference range study had not been performed and the reference ranges in use not been verified for the normal patient population.
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 review of the laboratory's Chemistry quality control records, quality assurance policy and procedure, observations, patient test records and interview of facility personnel, the laboratory failed to have a quality control program in place to detect immediate errors and errors over time for eighteen analytes tested on the Vitros 350 chemistry analyzer using the performance verifier controls. The findings included: 1. Review of Chemistry quality control records for January 2023 found the laboratory retained daily printouts for the two levels of controls. The instrument printouts for each of the quality control results did not include acceptable ranges on the printouts. The laboratory did not print Levy Jennings graphs or have another means to assess the quality control performance over time. Review of the Chemistry PV logs found a comment at the bottom of the page "Controls have passed for the month of Jan 2023" with the testing person's signature and the initials of the lab director. 2. Review of the laboratoryr's own policy titled Quality Assurance Policies and Procedures found: " General Quality Policies 1. Quality in the entire test system is of foremost importance to this lab/ office. 2. All lab personnel are trained and properly commensurate with their positions, duties and responsibilities. 3. The lab maintains a quality control program to assure continued precision and accuracy of lab results. 4. This laboratory participates in HCFA approved proficiency testing program for all non-waived analyst tested." 3. Observations made in the laboratory found the laboratory did not utilize the quality control functions on the Vitros 250. Quality control files were not set up with lot numbers and acceptable ranges for each level of quality control materials used. Testing personnel tested quality control materials as patients using PV1 and PV2 as the patient identifiers. Analytes tested using the Vitros 350 were: Albumin Alkaline Phosphatase ALT AST Direct bilirubin Urea Nitrogen Calcium Cholesterol Chloride Creatinine D HDL Carbon Dioxide Glucose Potassium Sodium Total Bilirubin Total Protein Triglycerides 3. Review of patient test records found the laboratory recorded an annual volume of 56,432 chemistry tests. 4. During interview of testing person one on the CMS report 209 Laboratory Personnel report conducted February 14, 2023 at 1: 50 PM, she confirmed that she did not know how to set up quality control files in the Vitros 350 Chemistry analyzer, stating" no one ever showed her how". She went on to say that after her quality control results printed, she had to compare them to the assay sheets to determine if they were acceptable. She also confirmed that she did not have a means to detect errors over time. 45469 II. Based on a review of quality control (QC) documents, annual test volumes, and confirmed in an interview, the laboratory failed to have a system in place to monitor QC for accuracy and precision over time for two of two tests, TSH and Vitamin D, performed on the Qualigen FastPack analyzer for 2022. The findings include: 1. Review of the QC documents for the Qualigen FastPack analyzer use in TSH and Vitamin D patient testing included individual QC documentation every month. Surveyor queried for documentation that QC was being monitored for accuracy and precision over time, and none was provided. 2. Review of the laboratory test count had the following annual patient test volumes for TSH and Vitamin D on the Qualigen FastPack system for 2022: TSH: 907 Vitamin D: 1213 3. In an interview on 2/14/2023 at 11:25 am, in the laboratory, testing person (TP) 1 confirmed that the laboratory did not have a mechanism in place to monitor QC for accuracy and precision overtime for the Qualigen FastPack analyzer used in TSH and Vitamin D patient testing. Key: TSH - Thyroid stimulating hormone
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations

	Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, quality control records, patient test records, and interview of facility personnel, the laboratory failed to test negative and positive control material at least once per day patient samples were tested for the TOX Drug Screen,9460 panel on the Quidel Triage Pro analyzer for 12 of 13 days in December 2022. NOTE: THIS IS A REPEAT DEFICIENCY FROM THE 03/2022 INSPECTION The findings included: 1. Review of the Quidel Triage TOX Drug Screen 9460 manufacturer's instructions found under the heading "QUALITY CONTROL CONSIDERATIONS: Good Laboratory Practice suggests that external controls should be tested with each new lot or shipment of test materials, or every 30 days, and as otherwise required by your laboratory's standard quality control procedures. Users should follow government guidelines (for example, Federal, State or Local) and/or accreditation requirements for quality control." 2. A review of Urine Drug Screen Control logs for December 2022 found quality control procedures documented once on December 2, 2022. 3. Review of patient test records found the laboratory tested 27 patient specimens on 13 days in December 2022 without testing negative and positive controls as follows: December 1, 2022 - patients 341, 3342, and 556 December 5, 2022 - patients 3046, 4583, 1325 and 4601 December 6, 2022 - patients 754,2205 and 4127 December 7, 2022 - patients 146, 4347, 940, 3875 and 1148 December 15, 2022 - patient 3829 December 16, 2022 - patient 1048 and 2471 December 17, 2022 - patient 2862 December 21, 2022 - patient 3810 December 22, 2022 - patient 714 and 3991 December 23, 2022 - patient 1042 December 27, 2022 - patient 424 December 28, 2022 - patient 383 December 29, 2022 - patients 4146 and 3180 4. During an interview of testing person one on the CMS report 209 Laboratory Personnel Report conducted February 14, 2023 at 9:56 AM, she confirmed that she only tests negative and positive quality control materials once each 30 days of with each new lot.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratories policies and procedures, quality control records, patient test records, verification records, and confirmed in interview, the quality assessment system used by the laboratory failed to identify and correct problems in the analytic systems. (Refer to D 5401, D5421, D5441, and D5449)
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493.

	1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of proficiency testing records, laboratory policy, quality control records, quality assurance activities, and interview, the laboratory director failed to provide overall management and direction in in accordance with 493.1407 for proficiency testing, quality control programs, and quality assurance programs in 2022. The findings include: 1. The laboratory director failed to ensure that proficiency samples were tested in the same manner as it tests patient specimens in three of three testing events for 2022. (Refer to D6016) 2. The laboratory director failed to ensure that proficiency testing reports were reviewed to evaluate the laboratory's overall performance in one of three testing events for Hematology/ Coagulation. (Refer to D6018) 3. The laboratory director failed to ensure the quality control program is established and maintained to assure the quality of Chemistry, Toxicology, and Endocrinology results. (Refer to D6020) 4. the laboratory director failed to ensure that written policies and procedures were followed to monitor, assess, and correct problems identified in general laboratory system requirements at 493.1231 through 493.1236 in 2022 and 2023, and failed to identify and correct problems in the analytic systems based on a review of quality control records, patient test records, verification records, and confirmed in an interview. (Refer to D6021)
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 2022 Chemistry Core proficiency testing records, policies and procedures and interview of facility personnel the laboratory director failed to ensure that proficiency samples were tested in the same manner as it tests patient specimens in three of three testing events for 2022. (See D2006)
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:

	Review of the 2022 proficiency testing records and interview of facility personnel found that the laboratory director failed to ensure that proficiency testing reports were reviewed to evaluate the laboratory's overall performance in one of three testing events for Hematology/ Coagulation. (see D 5211)
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of quality control policies, procedures, and records, and interview with facility personnel, the Laboratory Director failed to ensure the quality control program is established and maintained to assure the quality of Chemistry, Toxicology, and Endocrinology results. (See D 5441, D 5449 and D 5401)
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of policies and procedures, proficiency testing records, quality assurance activities, and interview of facility personnel, the laboratory director failed to ensure that written policies and procedures were followed to monitor, assess, and correct problems identified in general laboratory system requirements at 493.1231 through 493.1236 in 2022 and 2023, and failed to identify and correct problems in the analytic systems based on review of quality control records, patient test records, verification records, and confirmed in interview. (Refer to D 5291 and D 5791)
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on a review of laboratory verification studies and the Centers for Medicare and Medicaid Services (CMS) personnel form 209, the technical consultant (TC) failed to

	document the review of the Sysmex XN-330 put into use for patient testing in December 2022. The findings include: 1. Review of the Sysmex Method Verification Manual, section 2 "Accuracy and Precision" had the following statement: "Analyzer accuracy and precision is checked during the calibration verification process and documented on the calibration certificate." 2. Review of the Certificate of Calibration had testing person (TP) 1, who could not be qualified as TC under 493.1411, signature of review on 11/21/2022, with no additional documentation of review by the TC listed on the CMS209.