Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D2167453	03/23/2021
Name of Provider or Supplier	**Street Address, City, State**	
Choice Rheumatology	6401 Sw Lee Blvd, Lawton, OK	

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 initial survey was performed on 03/22,23/2021. When the surveyors arrived, the business consultant for high complexity stated on 03/23/2021 at 11:00 am, the laboratory had ceased patient testing on 01/07/2021 due to a lack of testing personnel (the testing person terminated employment on 01/07/2021 and the laboratory was not able to find a replacement. The laboratory was planning to resume patient testing as soon as they were able to hire a qualified testing person. The business consultant for high complexity stated to the surveyors on 03/22/2021 at 11:30 am, patient testing had been performed from 09/03/2019 through 01/07/2021, therefore, the surveyors performed the initial survey for the time period patient testing had occurred since the laboratory was actively looking for a testing person and could resume testing at any time. The laboratory was found out of compliance with the following CLIA regulations: 493.801; D2000: ENROLLMENT AND TESTING OF SAMPLES 493.1250; D5400: ANALYTIC SYSTEMS 493.1403; D6000: LABORATORY DIRECTOR, MODERATE COMPLEXITY TESTING The findings were reviewed with the laboratory director at the conclusion of the survey.
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on a review of records and interview with the business consultant for high

	complexity, the laboratory failed to enroll in a proficiency testing program for Chemistry and Hematology testing. Findings include: (1) On 03/22/2021 at 11:45 am, the business consultant for high complexity stated the following to the surveyors: (a) The laboratory performed Albumin, Alkaline Phosphatase, AST (Aspartate Aminotransferase), ALT (Alanine Aminotransferase), BUN, Calcium, Chloride, Sodium, Creatinine, Glucose, Potassium, Total Bilirubin, CK (Creatine Kinase), and Uric Acid testing using the Pentra c400 analyzer from 09/16/2020 through 01/07 /2021; (b) The laboratory performed CBC (Complete Blood Count) testing, which included the analytes WBC (White Blood Cell), RBC (Red Blood Cell), Hemoglobin, Hematocrit, and Platelet Count from 09/16/2020 through 01/07/2021. (2) Surveyor #1 reviewed proficiency testing records for 2020 and to date in 2021. There was no evidence the laboratory had enrolled and participated in proficiency testing during the time testing had been performed. The following was identified: (a) The laboratory had not enrolled in proficiency testing until 11/30/2020, which was after the laboratory began patient testing; (b) The first events had been shipped by the proficiency testing program as follows: (i) First Event Chemistry Core had been shipped on 01/11/2021, which was after the laboratory temporarily discontinued testing because the testing person terminated employment on 01/07/2021, therefore, this event had not been tested; (ii) First Event Hematology had been shipped on 03/08/2021, which was after the laboratory temporarily discontinued testing because the testing person terminated employment on 01/07/2021, therefore, this event had not been tested. (3) Surveyor #1 reviewed the findings with the consultant for high complexity, who stated on 03/22 /2021 at 4:00 pm, the laboratory had not enrolled in proficiency testing until after they began patient testing.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on a review of records and interview with the business consultant for high complexity, the laboratory failed to have a written technical supervisor and technical consultant competency policy based on the position responsibilities as listed in Subpart M. Findings include: (1) On 03/22/2021, surveyor #1 reviewed personnel records for competency assessments performed during 2019 and 2020. There was no evidence of competencies performed for the technical supervisor and technical consultant based on their job responsibilities; (2) Surveyor #1 asked if a written policy to evaluate the technical supervisor and technical consultant based on job responsibilities was available. The business consultant for high complexity stated on 03/22/2021 at 12:12 pm, a policy had not been written and the above competencies had not been performed.
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 records, written policies and procedures, manufacturer's instructions, and interview with the business consultant for high complexity the laboratory failed to monitor and evaluate the overall quality of analytic systems. Findings include: (1) The laboratory failed to have written procedures for routine chemistry and hematology testing. Refer to D5401; (2) The laboratory failed to follow the manufacturer's instructions for verifying automated differential flags; and failed to follow the manufacturer's instructions for the validation process. Refer to D5411; (3) The laboratory failed to ensure an analyzer had been stored as required by the manufacturer. Refer to D5413; (4) The laboratory failed to ensure reagents had not exceeded their expiration date. Refer to D5417; (5) The laboratory failed to verify the reference ranges for a new Chemistry analyzer; and failed to ensure the demonstrated reportable ranges were utilized for Hematology and Chemistry testing. Refer to D5421; (6) The laboratory failed to follow the manufacturer's instructions for performing maintenance procedures for Chemistry and Hematology testing. Refer to D5429; (7) The laboratory failed to have control procedures that monitored the accuracy and precision of the testing process for Chemistry and Hematology testing. Refer to D5441; (8) The laboratory failed to follow the manufacturer's quality control specifications for Hematology testing. Refer to D5479.
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 written policies and procedures, and interview with the business consultant for high complexity, the laboratory failed to have written procedures for routine chemistry and hematology testing. Findings include: (1) On 03/22/2021 at 11: 30 am, the business consultant for high complexity stated the following to surveyor #1: (a) The laboratory performed testing using the Pentra c400 analyzer as follows: (i) Albumin, Alkaline Phosphatase, AST (Aspartate Aminotransferase), ALT (Alanine Aminotransferase), BUN, Calcium, Chloride CO2, Sodium, Creatinine, Glucose, Potassium, and Total Bilirubin testing had been performed from 09/16/2020 through 01/07/2021; (ii) CK (Creatine Kinase) and Uric Acid testing had been added to the test menu on 10/06/2020 and CRP (C-Reactive Protein) testing had been added to the test menu on 10/15/2020 and tested through 01/07/2021. (b) The laboratory performed CBC (Complete Blood Count) testing from 02/28/2020 through 01/07/2021. (2) Surveyor #1 requested the procedure manuals for the testing. The business consultant for high complexity stated on 03/22/2021 at 02:28 pm, a procedure manual was not available for the above testing.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)

Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

This STANDARD is not met as evidenced by:
Based on a review of records, manufacturer's instructions, and interview with the business consultant for high complexity, the laboratory failed to follow the manufacturer's instructions for verifying automated differential flags for 25 of 32 patient reports; and failed to follow the manufacturer's instructions for the validation process for one of one new analyzers Findings include: AUTOMATED FLAGS (1) On 03/22/2021 at 11:30 am, the business consultant for high complexity stated the following to surveyor #1: (a) The laboratory performed routine CBC (Complete Blood Count) testing using the Pentra 60c+ analyzer and available for patient use on 02/28 /2020 (the laboratory temporarily discontinued testing on 01/07/2021 because the testing person terminated employment). (2) On 03/23/2021, surveyor #2 reviewed the manufacturer's operator's manual for information regarding flagged results which stated: (a) "Verification of any abnormal test result (including flagged results or results outside of the normal range) should be performed using reference methods or other standard laboratory procedures for conclusive verification of the results; (b) Examples of specimen flags include the following: (i) L1, LL, LL1 - Erythroblasts suspected (ii) ! - Abnormal White Blood Cell suspected (3) Surveyor #2 then reviewed patient records and identified that for 25 of 32 records reviewed between 12 /22/2020 through 01/07/2021, the laboratory had not verified the results when automated differential flags were obtained as follows: (a) [L1] flag obtained on a patient sample tested on 12/22/2020 at 02:24 pm; (b) [L1] flag obtained on a patient sample tested on 12/22/2020 at 02:50 pm; (c) [LL, L1] flag obtained on a patient sample tested on 12/22/2020 at 03:45 pm; (d) [LL, L1] flag obtained on a patient sample tested on 12/23/2020 at 08:21 am; (e) [LL, L1] flag obtained on a patient sample tested on 12/23/2020 at 03:55 pm; (f) [LL, L1] flag obtained on a patient sample tested on 12/23/2020 at 09:09 am; (g) [LL, L1] flag obtained on a patient sample tested on 12/23/2020 at 01:10 pm; (h) [LL] flag obtained on a patient sample tested on 12/23/2020 at 02:08 pm; (i) [LL] flag obtained on a patient sample tested on 12/23/2020 at 01:30 pm; (j) [LL1] flag obtained on a patient sample tested on 12/28 /2020 at 03:06 pm; (k) [LL, L1] flag obtained on a patient sample tested on 12/28 /2020 at 10:49 am; (l) [LL] flag obtained on a patient sample tested on 12/29/2020 at 01:38 pm; (m) [!] flag obtained on a patient sample tested on 12/30/2020 at 09:14 am; (n) [LL] flag obtained on a patient sample tested on 12/31/2020 at 01:22 pm; (o) [!] flag obtained on a patient sample tested on 12/31/2020 at 12:00 pm; (p) [!] flag obtained on a patient sample tested on 12/31/2020 at 03:00 pm; (q)[!] flag obtained on a patient sample tested on 12/31/2020 at 03:09 pm; (r) [!] flag obtained on a patient sample tested on 01/04/2021 at 10:34 am; (s) [!] flag obtained on a patient sample tested on 01/05/2021 at 02:11 pm; (t) [!] flag obtained on a patient sample tested on 01 /05/2021 at 02:16 pm; (u)[!] flag obtained on a patient sample tested on 01/06/2021 at 08:45 am; (v)[!] flag obtained on a patient sample tested on 01/06/2021 at 10:55 am; (w) [!] flag obtained on a patient sample tested on 01/06/2021 at 02:04 pm; (x) [!] flag obtained on a patient sample tested on 01/06/2021 at 02:19 pm; (y) [!] flag obtained on a patient sample tested on 01/07/2021 at 03:21 pm; (4) The findings were reviewed with the business consultant for high complexity. The business consultant of high complexity stated on 03/28/2021 at 11:45 am, the laboratory had not followed the manufacturer's instructions as indicated above. VALIDATION PROCESS OF A NEW INSTRUMENT (1) On 03/22/2021 at 11:30 am, the business consultant for

	high complexity stated the following to surveyor #1: (a) The laboratory performed routine CBC (Complete Blood Count) testing using the Pentra 60c+ analyzer and available for patient use on 02/28/2020 (the laboratory temporarily discontinued testing on 01/07/2021 because the testing person terminated employment). (2) On 03 /22/2021, surveyor #2 reviewed the manufacturer's operator's Validation Process which stated the following: (a) "Step 1 - Precision" (i) "Test at least five repetitions of at least two samples with different values."; (b) "Step 3 - Reference" (i) "Collect specimens from a minimum of 10 normal patients." (ii) "Test each specimen once, spread the testing over a minimum of 3 days."; (iii) "Compare this range to the manufacturer's range"; (iv) "If comparable, the laboratory's range falls within the manufacturer's range. Perform the test again when 20 or 30 normal patient results are obtained to see if the reference range needs adjusting.". (3) Surveyor #2 then reviewed the performance specification records and identified the following: (a) Precision (i) On 02/27/2020, the laboratory performed four repetitions. (b) Reference (i) On 02/27 /2020, the laboratory tested four patient samples over one day; (ii) There was no evidence the laboratory compared the ranges to the manufacturer's range and tested 20 or 30 additional patient samples. (4) Surveyor #2 reviewed the findings with the business consultant of high complexity who stated on 03/22/2021 at 02:10 pm, the laboratory had not followed the manufacturer's instructions as indicated above.
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 a review of records, manufacturer's instructions, and interview with the business consultant for high complexity, the laboratory failed to ensure an analyzer had been stored as required by the manufacturer for two of three months. Findings include: (1) On 03/22/2021 at 11:30 am, the business consultant for high complexity stated the following to surveyor #1: (a) The laboratory performed routine CBC (Complete Blood Count) testing using the Pentra 60c+ analyzer from 02/28/2020 through 01/07/2021; (2) Surveyor #2 reviewed the manufacturer's environmental requirements, which required the following: (a) Room temperature 16 - 34 degrees C (Celsius) or 61 -93 degrees F (Fahrenheit); (b) Maximum humidity of 80%. (3) Surveyor #2 reviewed laboratory temperature records and humidity records from October 2020 through December 2020 and identified room temperatures and humidity were not documented as taken for the following days: (a) October 2020 - Eight of 16 days of patient testing (days: 1,5,6,7,8,12,13,14); (b) December 2020 - One of 16 days of patient testing (day: 31). (4) On 03/23/2021, surveyor #2 reviewed the records with the business consultant for high complexity. The business consultant for high complexity stated on 03/23/2021 at 10:35 am the room temperature and humidity had not been documented as indicated above.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)

	Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on a review of records and interview with the business consultant for high complexity, the laboratory failed to ensure reagents had not exceeded their expiration date for 15 of 15 days. Findings include: (1) On 03/22/2021 at 11:30 am, the business consultant for high complexity stated the following to surveyor #1: (a) The laboratory performed routine CBC (Complete Blood Count) testing using the Pentra 60c+ analyzer from 02/28/2020 through 01/07/2021. (2) On 03/22/2021 at 11:45 am, surveyor #2 observed three levels of quality control materials in the laboratory refrigerator: (a) Horiba Difftrol Hematology Low Control - Lot# PX427L with an expiration date of 03/05/2021; (b) Horiba Difftrol Hematology Normal Control - Lot# PX427N with an expiration date of 03/05/2021; (c) Horiba Difftrol Hematology High Control - Lot# PX427H with an expiration date of 03/05/2021. (3) Surveyor #2 showed the quality control materials to the business consultant for high complexity. The business consultant for high complexity stated on 03/22/2021 at 12:00 that patients had not been tested since 01/07/2021 but would resume testing when personnel were hired and expired controls were available for use as indicated above.
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 records and interview with the business consultant for high complexity, the laboratory failed to verify the reference ranges; and failed to ensure the demonstrated reportable ranges were utilized for Chemistry testing. Findings include: (1) On 03/22/2021 at 11:30 am, the business consultant for high complexity stated the following to surveyor #1: (a) The laboratory began performing Albumin, Alkaline Phosphatase, AST (Aspartate Aminotransferase), ALT (Alanine Aminotransferase), BUN, Calcium, Chloride CO2, Sodium, Creatinine, Glucose, Potassium, Total Bilirubin testing using the Pentra c400 analyzer on 09/16/2020 (the laboratory temporarily discontinued testing on 01/07/2021 because the testing person terminated employment); (2) Surveyor #1 reviewed the performance specification records with the following identified: (a) There was no evidence the reference ranges (normal ranges) had been verified for each analyte; (b) The reportable ranges that had been demonstrated for each analyte, did not match the manufacturer's reportable ranges as follows: (i) Albumin - The laboratory demonstrated a reportable range of 1.3-5.6 g/dl and the manufacturer's reportable range was 0.46-5.6 g/dl; (ii) Calcium - The laboratory demonstrated a reportable range of 1.1-17.1 mg/dl and the manufacturer's reportable range was 0.64-18.05 mg/dl; (iii) Chloride - The laboratory

	demonstrated a reportable range of 82-207 mmol/L and the manufacturer's reportable range was 70-200 mmol/L; (iv) CO2 - The laboratory demonstrated a reportable range of 6-38 mmol/L and the manufacturer's reportable range was 1.8-56.9 mmol/L; (v) Glucose - The laboratory demonstrated a reportable range of 6-814 mg/dl and the manufacturer's reportable range was 3.96-900 mg/dl; (vi) Creatinine - The laboratory demonstrated a reportable range of 0.51-25.54 mg/dl and the manufacturer's reportable range was 0.22-18.08 mg/dl; (vii) Sodium - The laboratory demonstrated a reportable range of 82-197 mmol/L and the manufacturer's reportable range was 110-200 mmol/L; (viii) Total Protein - The laboratory demonstrated a reportable range of 1.8-9.4 g/dl and the manufacturer's reportable range was 0.65-16.0 g/dl. (3) Surveyor #1 reviewed the data with the business consultant for high complexity and asked if there was data to prove the laboratory verified the reference ranges and if the laboratory had been using the reportable ranges as demonstrated above since they were not identical to the manufacturer's reportable ranges. (NOTE: Since a procedure manual was not available for the testing (Refer to D5401), surveyor #1 was not able to determine the reportable ranges that had been used by the laboratory). The business consultant for high complexity stated on 03/22/2021 at 03:05 pm, the reference ranges had not been verified by the laboratory and it could not be determined if the laboratory had utilized the reportable ranges they had demonstrated. 39088 Based on a review of records and interview with the business consultant for high complexity, the laboratory failed to ensure the demonstrated reportable ranges were utilized for one of one new methods of Hematology testing. Findings include: (1) On 03/22/2021 at 11: 30 am, the business consultant for high complexity stated the following to surveyor #1: (a) The laboratory performed routine CBC (Complete Blood Count) testing using the Pentra 60c+ analyzer and available for patient use on 02/28/2020 (the laboratory temporarily discontinued testing on 01/07/2021 because the testing person terminated employment). (2) Surveyor #2 reviewed the performance specification records with the following identified: (a) The reportable ranges that had been demonstrated for each analyte, did not match the manufacturer's reportable ranges as follows: (i) Hemoglobin - The laboratory demonstrated a reportable range of 0.6 - 24.64 g/dl and the manufacturer's reportable range was 0.0 - 31.06 g/dl; (ii) Hematocrit - The laboratory demonstrated a reportable range of 2.36 - 68.51% and the manufacturer's reportable range was 1.8 - 88.9%. (3) On 03/23/2021, surveyor #2 reviewed the data with the business consultant for high complexity and asked if there was data to prove the laboratory if the laboratory had been using the reportable ranges as demonstrated above since they were not identical to the manufacturer's reportable ranges. (NOTE: Since a procedure manual was not available for the testing (Refer to D5401), surveyor #2 was not able to determine the reportable ranges that had been used by the laboratory). The business consultant for high complexity stated on 03/22/2021 at 02: 55 pm, the laboratory had not utilized the reportable ranges the laboratory had demonstrated.
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 a review of records, manufacturer's instructions, and interview with the business consultant for high complexity, the laboratory failed to follow the

	manufacturer's instructions for performing maintenance procedures for 4 of 4 months. Findings include: (1) On 03/22/2021 at 11:45 am, the business consultant for high complexity stated the following to the surveyors: (a) Albumin, Alkaline Phosphatase, ALT (Alanine Amino Transferase), AST (Aspartate Amino Transferase), BUN (Blood Urea Nitrogen), Calcium, Chloride, CO2, Creatinine, Glucose, Potassium, Sodium, Total Bilirubin, Total Protein, and Cholesterol testing had been performed on the ABX Pentra c400 analyzer from 09/16/2020 through 01/07/2021; (b) CK (Creatine Kinase) and Uric Acid testing had been added to the test menu on 10/06 /2020 and CRP (C-Reactive Protein) testing had been added to the test menu on 10/15 /2020 and all were tested through 01/07/2021. (2) Surveyor #1 reviewed the manufacturer's maintenance requirements as stated on the manufacturer's maintenance log for the analyzer, which required the following: (a) Bi-Monthly (i) Filter Lee replacement (ii) Glycol level check (b) Monthly (i) Wash Tower Cleaning with Deproteinizer (ii) Syringe Plunger Tip Replacement (Sample & Reagent) (iii) Pressure Sensor Calibration (Sample & Reagent) (iv) Cleaning the Cooling Unit Condenser (v) Precitest After Syringe Tip Replacement (3) Surveyor #1 then reviewed maintenance records for 4 months (September 2020 through December 2020). The maintenance had not been documented as performed as follows: (a) Bi-Monthly - Filter Lee Replacement had not been documented as performed during the review period; (b) Monthly - Syringe Plunger Tip Replacement and Pressure Sensor Calibration had not been documented as performed during the review period. (4) Surveyor #1 reviewed the records with the business consultant for high complexity who stated on 03/22 /2021 at 2:00 pm, the maintenance had not been performed as indicated above; (5) Refer to D5441 for examples of patient Chemistry testing performed when the above maintnance procedures had not been documented as performed. 39088 Based on a review of records, manufacturer's instructions, and interview with the business consultant for high complexity, the laboratory failed to follow the manufacturer's instructions for performing maintenance procedures for five of five months. Findings include: (1) On 03/22/2021 at 11:30 am, the business consultant for high complexity stated the following to surveyor #1: (a) The laboratory performed routine CBC (Complete Blood Count) testing using the Pentra 60c+ analyzer from 02/28/2020 through 01/07/2021; (2) On 03/23/2021, surveyor #2 reviewed the manufacturer's maintenance requirements as stated on the manufacturer's maintenance log for the analyzer, which required the following: (a) Daily Maintenance (i) Check reagent levels (ii) Check printer paper (iii) Ck waste level, empty if needed (iv) Perform daily start-up (v) Run controls (vi) Daily shutdown (b) Monthly Maintenance (i) Perform Concentrated Cleaning (ii) Empty cap piercing filter (3) Surveyor #2 then reviewed maintenance records for five months (September 2020 through January 2021) and identified the maintenance had not been documented as performed during the review period; (4) Surveyor #2 reviewed the records with the business consultant for high complexity who stated on 03/23/2021 at 11:00 am, the maintenance had not been performed as indicated above; (5) Refer to D5441 for examples of patient CBC testing performed when maintenance procedures had not been performed.
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:
Based on a review of records and interview with the business consultant for high complexity and the laboratory director, the laboratory failed to have control procedures that monitored the accuracy and precision of the testing process for Chemistry testing for 4 of 4 months. Findings include: (1) On 03/22/2021 at 11:45 am, the business consultant for high complexity stated to the surveyors Albumin, Alkaline Phosphatase, ALT (Alanine Amino Transferase), AST (Aspartate Amino Transferase), BUN (Blood Urea Nitrogen), Calcium, Chloride, CO2, Creatinine, Glucose, Potassium, Sodium, Total Bilirubin, Total Protein, and Cholesterol testing had been performed on the ABX Pentra c400 analyzer from 09/16/2020 through 01/07 /2021; (2) On 03/23/3021 at 12:50 pm, the laboratory director stated to surveyor #1 that two levels of QC (quality control) materials had been performed each day of patient testing; (3) Surveyor #1 requested QC records (i.e., Levey-Jennings data) for the above testing performed from 09/16/2020 though 01/07/2021 to ensure QC had been monitored for variances (i.e. shifts, trends, biases). The laboratory director stated on 03/23/2021 at 01:00 pm, there were no records (i.e., Levey-Jennings data) proving the control results had been monitored for variances during the review period because data had not been printed and maintained. The laboratory director was able to retrieve the Levey-Jennings data from the analyzer's memory for the surveyor's review, for testing performed from September 2020 through January 2021. Surveyor #1 was able to verify that QC had been performed each day of patient testing, however, there was no documentation the data had been reviewed for variances by the laboratory; (4) The following were examples of patient CMP* testing performed when the QC had not been monitored for variances: (a) Patient #3808 - Testing performed on 10/29/2020 (b) Patient #4486 - Testing performed on 11/24/2020 (c) Patient #4515 - Testing performed on 11/25/2020 (d) Patient #4407 - Testing performed on 12/02/2020 (e) Patient #4462 - Testing performed on 12/10/2020 (f) Patient #3318 - Testing performed on 12/15/2020 (g) Patient #2911 - Testing performed on 12/22/2020 (h) Patient #571 - Testing performed on 12/29/2020 (i) Patient #4412 - Testing performed on 12/31/2020 (j) Patient #1034 - Testing performed on 01/04/2021 (k) Patient #2298 - Testing performed on 01/05/2021 (l) Patient #4006 - Testing performed on 01/06 /2021 (m) Patient #1930 - Testing performed on 01/07/2021 39088 Based on a review of records and interview with the business consultant for high complexity and the laboratory director, the laboratory failed to have control procedures that monitored the accuracy and precision of the testing process for Hematology testing for four of four months. Findings include: (1) On 03/22/2021 at 11:30 am, the business consultant for high complexity stated the following to surveyor #1: (a) The laboratory performed routine CBC (Complete Blood Count) testing using the Pentra 60c+ analyzer from 02 /28/2020 through 01/07/2021; (2) On 03/23/3021 at 12:50 pm, the laboratory director stated to surveyor #2 that three levels of QC (quality control) materials had been performed each day of patient testing; (3) Surveyor #2 requested QC records (i.e., Levey-Jennings data) for the above testing performed from 10/22/2020 though 01/07 /2021 to ensure QC had been monitored for variances (i.e. shifts, trends, biases). The laboratory director stated on 03/23/2021 at 01:10 pm, there were no records (i.e., Levey-Jennings data) proving the control results had been monitored for variances during the review period because data had not been printed and maintained. The laboratory director was able to retrieve the Levey-Jennings data from the analyzer's

	memory for the surveyor's review, for testing performed from October 2020 through January 2021. Surveyor #2 was able to verify that QC had been performed each day of patient testing, however, there was no documentation the data had been reviewed for variances by the laboratory; (4) The following were examples of patient CBC testing performed when the QC had not been monitored for variances: (a) Patient #4345 - Testing performed on 10/22/2020 at 11:44 am (b) Patient #4361 - Testing performed on 10/28/2020 at 03:12 pm (c) Patient # 4408 - Testing performed on 10/29/2020 at 02:05 pm (d) Patient #917- Testing performed on 11/02/2020 at 08:41 am (e) Patient #3832 - Testing performed on 11/04/2020 at 11:15 am (f) Patient #1123 - Testing performed on 11/05/2020 at 09:00 am (g) Patient #3216 - Testing performed on 11/09 /2020 at 11:35 am (h) Patient #4466 - Testing performed on 11/11/20 at 09:22 am (i) Patient #1350 - Testing performed on 11/12/2020 at 04:15 pm (j) Patient #4389 - Testing performed on 11/16//2020 at 11:33 am (k) Patient #3976 - Testing performed on 11/17/2020 at 03:41 pm (l) Patient #4494 - Testing performed on 11/18/2021 at 02: 14 pm (m) Patient #2299 - Testing performed on 11/19/2021 at 02:05 pm (n) Patient #4491 - Testing performed on 11/23/2020 at 01:39 pm (o) Patient #2346 - Testing performed on 11/24/2020 at 03:57 pm (p) Patient #4520 - Testing performed on 11/25 /2020 at 08:35 am (q) Patient #3988 - Testing performed on 11/20/2020 at 03:39 pm (r) Patient #1848 - Testing performed on 12/09/2020 at 03:55 pm (s) Patient #4462 - Testing performed on 12/10/2020 at 08:30 am (t) Patient #1294 - Testing performed on 12/14/2020 at 02:00 pm (u) Patient #4568 - Testing performed on 12/16/2020 at 02: 33 pm (v) Patient #4582 - Testing performed on 12/22/2020 at 02:24 pm (w) Patient #2857 - Testing performed on 12/23/2020 at 01:10 pm (x) Patient #3679 - Testing performed on 12/28/2020 at 03:17 pm (y) Patient #2251 - Testing performed on 12/29 /2020 at 10:00 am (z) Patient #1510 - Testing performed on 12/30/2020 at 9:14 am
D5479	CONTROL PROCEDURES CFR(s): 493.1256(e)(5)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the business consultant for high complexity, the laboratory failed to follow the manufacturer's quality control specifications for Hematology testing for one of one lot numbers. Findings include: (1) On 03/22/2021 at 11:30 am, the business consultant for high complexity stated to surveyor #1 the laboratory performed routine CBC (Complete Blood Count) testing using the Pentra 60c+ analyzer from 02/28/2020 through 01/07/2021; (2) On 03/23/3021 at 12:50 pm, the laboratory director stated to surveyor #2 that three levels of QC (quality control) materials had been performed each day of patient testing; (3) Surveyor #2 reviewed the manufacturer's instructions for the QC (quality control) materials which stated: (a) "The mean assay values of each ABX Difftrol parameter are obtained from replicated assays performed on analysers that have calibrated using whole blood. The assays were performed using reagents recommended by Horiba Medical. Values obtained with ABX Difftrol (if used before its expiry date) should fall within the expected range. The expected ranges are representative of estimates of the variation between different laboratories for each parameters. Inter-laboratory variations are the consequence of instrument calibrations, maintenance, and operating technique. The reference results are therefore only

	indicative for control purposes and should not be used for calibration. At least five consecutive analyses, on a a correctly calibrated analyser, are needed to establish the assay means and standard deviations for each ABX Difftrol parameter.". (4) Surveyor #2 reviewed records for testing performed from 09/23/2020 through 12/31/2020. For one of one lot number, the following was identified: (a) ABX Difftrol Lot #PX427L, PX427N, PX427H - the means and range were the same as the previous quality control lot#PX425L, PX425N, PX425H (5) The surveyor reviewed the findings with the laboratory director. The laboratory director stated on 03/23/2021 at 03:45 pm the laboratory had not established the laboratory mean and ranges with a new lot change as indicated above; (6) Refer to D5441 for examples of patient CBC testing when the laboratory failed to follow the manufacturer's instructions for establishing means and ranges.
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 a review of records, written policies and procedures, manufacturer's instructions, and interview with the business consultant for high complexity the laboratory failed to monitor and evaluate the overall quality of analytic systems. Findings include: (1) It was determined the laboratory did not have an effective mechanism for performing analytic quality assessment because of the following issues identified during the survey: (a) The laboratory failed to have written procedures for routine chemistry and hematology testing. Refer to D5401; (b) The laboratory failed to follow the manufacturer's instructions for verifying automated differential flags; and failed to follow the manufacturer's instructions for the validation process. Refer to D5411; (c) The laboratory failed to ensure an analyzer had been stored as required by the manufacturer. Refer to D5413; (d) The laboratory failed to ensure reagents had not exceeded their expiration date. Refer to D5417; (e) The laboratory failed to verify the reference ranges for a new Chemistry analyzer; and failed to ensure the demonstrated reportable ranges were utilized for Hematology and Chemistry testing. Refer to D5421; (f) The laboratory failed to follow the manufacturer's instructions for performing maintenance procedures for Chemistry and Hematology testing. Refer to D5429; (g) The laboratory failed to have control procedures that monitored the accuracy and precision of the testing process for Chemistry and Hematology testing. Refer to D5441; (h) The laboratory failed to follow the manufacturer's quality control specifications for Hematology testing. Refer to D5479.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by:

	Based on a review of a patient report and interview with the business consultant for high complexity, the laboratory failed to provide a normal reference range for one of one patient test report. Findings include: (1) On 03/22/2021 at 11:30 am, the business consultant for high complexity stated the following to surveyor #1: (a) The laboratory performed routine CBC (Complete Blood Count) testing using the Pentra 60c+ analyzer from 02/28/2020 through 01/07/2021. (2) Surveyor #2 reviewed one test report for a patient tested on 12/10/2020 at 12:54 pm. The report did not include a normal reference range for the following analytes: (a) Neutrophils - percent and absolute number; (b) Lymphocytes - percent and absolute number; (c) Monocytes - percent and absolute number; (d) Eosinophils - percent and absolute number; (e) Basophils - percent and absolute number. (3) Surveyor #2 reviewed the patient test report with the business consultant for high complexity. The business consultant for high complexity stated on 03/22/2021 at 04:20 pm, the patient test report did not included a normal reference range as indicated above.
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 a review of records, manufacturer's instructions, and interview with the business consultant for high complexity, the laboratory director failed to provide overall management and direction for moderate complexity testing. Findings include: (1) The laboratory director failed to ensure verification procedures for new test systems were adequate to determine the performance characteristics. Refer to D6013; (2) The laboratory director failed to ensure test methods were performed as required by the manufacturer to ensure accurate and reliable results were reported. Refer to D6014; (3) The laboratory director failed to ensure a quality control program was maintained to ensure the quality of laboratory services. Refer to D6020; (4) The laboratory director failed to ensure a quality assessment program had been established and maintained. Refer to D6021; (5) The laboratory director failed to ensure test reports included pertinent information required for interpretation. Refer to D6026; (6) The laboratory director failed to ensure policies and procedures were available. Refer to D6031.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on a review of records and interview with the business consultant for high

	complexity, the laboratory director failed to ensure verification procedures for new test systems were adequate to determine the performance characteristics. Findings include: (1) The laboratory director failed to ensure the laboratory verified the reference ranges for Chemistry testing; and failed to ensure the demonstrated reportable ranges were utilized for Hematology and Chemistry testing. Refer to D5421.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(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)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the business consultant for high complexity, the laboratory director failed to ensure test methods were performed as required by the manufacturer to ensure accurate and reliable results were reported. Findings include: (1) The laboratory director failed to ensure the manufacturer's instructions werre followed for verifying automated differential flags; and failed to follow the manufacturer's instructions for the validation process. Refer to D5411; (2) The laboratory director failed to ensure reagents had not exceeded their expiration date. Refer to D5417; (3) The laboratory director failed to ensure the manufacturer's instructions were followed for performing maintenance procedures for Chemistry and Hematology testing. Refer to D5429.
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 a review of records, manufacturer's instructions, and interview with the business consultant for high complexity, the laboratory director failed to ensure a quality control program was maintained to ensure the quality of laboratory services. Findings include: (1) The laboratory director failed to ensure an analyzer had been stored as required by the manufacturer. Refer to D5413; (2) the laboratory director failed to ensure control procedures monitored the accuracy and precision of the testing process for Chemistry and Hematology testing. Refer to D5441; (3) The laboratory director failed to ensure the laboratory followed the manufacturer's quality control specifications for Hematology testing. Refer to D5479.
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 a review of records, written policies and procedures, manufacturer's instructions, and interview with the business consultant for high complexity, the laboratory director failed to ensure a quality assessment program had been established and maintained. Findings include: (1) The laboratory director failed to ensure the laboratory had an ongoing mechanism for performing effective analytic quality assessment. Refer to D5791.
D6026	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(8) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(8) Ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Based on a review of a patient report and interview with the business consultant for high complexity, the laboratory director failed to ensure test reports included pertinent information required for interpretation. Findings include: (1) The laboratory director failed to ensure appropriate reference ranges were available for CBC testing. Refer to D5807.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on a review of written policies and procedures, and interview with the business consultant for high complexity, the laboratory director failed to ensure policies and procedures were available. Findings include: (1) The laboratory director failed to ensure written procedures for routine chemistry and hematology testing. Refer to D5401.