Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0656628	12/12/2018
Name of Provider or Supplier	**Street Address, City, State**	
Seiling Municipal Hospital	809 Ne Hwy 60, Seiling, 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 recertification survey was performed 12/10/2018 - 12/12/2018. The laboratory was found to be in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory manager and the hospital administrator at the conclusion of the survey.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory failed to thoroughly review and evaluate proficiency testing results. Findings include: (1) On the first day of the survey, the surveyor reviewed the 2017 and 2018 proficiency testing records and identified the following biases (the biases were identified using the SDI (Standard Deviation Index) values assigned by the proficiency testing program): (a) First 2017 Hematology Event (i) WBC (White Blood Count): 5 of 5 results exhibited a Negative bias (aa) XE-01: SDI -1.3 (bb) XE-02: SDI -1.9 (cc) XE-03: SDI -1.6 (dd) XE-04: SDI -2.6 (ee) XE-05: SDI -2.8 (b) Third 2017 Chemistry Event: (i) pH: 4 of 5 results exhibited a Negative bias (aa) BG-12: SDI -2.4 (bb) BG-13: SDI -2.8 (cc) BG-14: SDI -2.3 (dd) BG-15: SDI -2.2 (c) Second 2018 Chemistry Event: (i) Amylase: 4 of 5 results exhibited a Positive bias (aa) CH-06: SDI 3.8 (bb) CH-07: SDI 1.3 (cc) CH-08: SDI 1.5 (dd) CH-10: SDI 2.4 (ii) AST (Aspartate Aminotransferase): 4 of 5 results exhibited a Positive bias (aa) CH-06: SDI 2.0 (bb) CH-07: SDI 2.6 (cc) CH-09: SDI 2.2 (dd) CH-10: SDI 2.5 (iii) BUN: 4 of 5 results exhibited a Positive bias (aa) CH-06: SDI 2.7 (bb) CH-08: SDI 1.0 (cc) CH-09: SDI 1.4 (dd) CH-10: SDI 3.5 (iv) Calcium: 4 of 5 results exhibited a Positive bias (aa) CH-06: SDI 3.9 (bb) CH-07: SDI 4.3 (cc) CH-09: SDI 3.2 (dd) CH-10: SDI 3.1 (v) Uric Acid: 4 of 5 results exhibited a Positive bias (aa) CH-06: SDI 3.9 (bb) CH-07:

	SDI 2.9 (cc) CH-09: SDI 2.3 (dd) CH-10: SDI 2.8 (d) Third 2018 Chemistry Event (i) Albumin: 3 of 5 results exhibited a Positive bias (aa) CH-13: SDI 2.9 (bb) CH-14: SDI 2.0 (cc) CH-15: SDI 2.6 (ii) Chloride: 4 of 5 results exhibited a Positive bias (aa) CH-11: SDI 2.7 (bb) CH-13: SDI 2.6 (cc) CH-14: SDI 3.1 (dd) CH-15: SDI 3.3 (iii) Potassium: 3 of 5 results exhibited a Positive bias (aa) CH-11: SDI 1.8 (bb) CH-13: SDI 2.0 (cc) CH-15: SDI 2.4 (iv) Sodium: 4 of 5 results exhibited a Positive bias (aa) CH-11: SDI 2.2 (bb) CH-13: SDI 2.1 (cc) CH-14: SDI 2.3 (dd) CH-15: SDI 2.4 (2) There was no documentation found in the records the laboratory identified and evaluated the biases to determine if a systematic failure had occurred, and there was no documentation the laboratory took corrective action (e.g., reviewed quality control record, maintenance records, calibration, patient results affected, etc.) for the biases; (3) The surveyor reviewed the findings with the laboratory manager who stated to the surveyor the laboratory had not identified or evaluated the biases, and corrective action had not been taken. NOTE: D5211 was cited at the previous recertification survey performed 03/28/17-03/30/17.
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 a review of records and interview with the laboratory manager, the laboratory failed to evaluate the accuracy of testing when proficiency testing results had not been graded by the proficiency testing program. Findings include: (1) On the first day of the survey, the surveyor reviewed the 2017 and 2018 proficiency testing records and identified the laboratory did not address results not graded by the proficiency testing program. The findings follow: (a) First 2017 Hematology Event - Blood Cell Identification (Educational): (i) BCI-06: (aa) The laboratory reported "Lymphocyte, reactive variant;" (bb) The proficiency testing program had not graded the result due to it being an "Educational challenge;" (cc) In addition, the proficiency testing program's expected response, was "See Commentary." (ii) BCI-07: (aa) The laboratory reported "Hypochromic Red Blood Cell;" (bb) The proficiency testing program had not graded the result due to it being an "Educational challenge;" (cc) In addition, the proficiency testing program's expected response, was "See Commentary." (b) First 2018 Chemistry Event - LDL (Low Density Lipoprotein) (i) CH-02: (aa) The laboratory reported "0;" (bb) The proficiency testing program had not graded the result due to "No appropriate peer group;" (cc) In addition, the proficiency testing program's expected response, was "See Data Summary." (c) Second 2018 Hematology Event - Blood Cell Identification: (i) BCI-10: (aa) The laboratory reported "Neutrophil, Hypersegmented;" (bb) The proficiency testing program had not graded the result due to "No consensus among the participants;" (cc) In addition, the proficiency testing program's expected response, was "See Commentary." (2) There was no evidence in the records the laboratory identified the non-graded results, obtained, and reviewed the commentary or data summary to evaluate their results; (3) The surveyor reviewed the records with the laboratory manager, who stated to the surveyor the non-graded proficiency testing results listed above had not been identified and had not been evaluated.

D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on a review of written policies and procedures, and interview with the laboratory manager, the laboratory failed to ensure a policy had been approved, signed, and dated by the laboratory director before use. Findings include: (1) On the first day of the survey, the laboratory manager stated the following to the surveyor: (a) The laboratory performed D-dimer and Troponin I testing using the Alere Triage Meter Pro and test cartridges; (b) An IQCP (Individualized Quality Control Plan) had been developed for the testing. (2) The surveyor reviewed the IQCP (dated as effective on 10/01/18) and identified the QCP (Quality Control Plan) had not been approved, signed, and dated by the laboratory director; (3) The surveyor reviewed the records with the laboratory manager who stated the QCP had not been approved, signed, and dated by the laboratory director before being put into use.
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 laboratory manager, the laboratory failed to follow the manufacturer's instructions for verifying flagged hematology results. Findings include: (1) On the first day of the survey, the laboratory manager stated to the surveyor: (a) CBC (Complete Blood Count) (e.g., WBC (White Blood Cell), RBC (Red Blood Cell), Hematocrit, Hemoglobin, Platelet, etc.) testing, which included a 5-part automated differential, was performed on the Sysmex XS-1000i analyzer; (b) Manual WBC differentials and peripheral smear reviews were performed on CBC's with results which met certain criteria or obtained flags. (2) The surveyor reviewed the manufacturer's operator's manual regarding flagged results and identified the following instructions: (a) NRBC? (i) Presence of nucleated RBC's possible (ii) Verify presence on slide, correct WBC count if necessary (b) Atypical Lymphocyte (i) Presence of atypical lymphocytes possible (ii) Perform manual differential (c) Immature Grans? (i) Presence of immature granulocytes possible (ii) Perform manual differential (d) Abn Lympho /Blasts? (i) Presence of atypical lymphocytes and/or blasts possible (ii) Perform manual differential (e) WBC ABN Scattergram (i) Abnormal WBC presentation on scattergram; (ii) Perform manual differential. (f) Left Shift? (i) Presence of "band" granulocytes possible; (ii) Perform manual differential. (g) PLT Abn Distribution (i) Presence of interfering particles in PLT histogram, i.e. Clumped platelets, fragmented RBC's, or microcytic RBC's; (ii) Verify presence on slide. If RBC or platelet clumps present, recollect sample if possible. Perform PLT estimate to confirm count. (h) HGB (Hemoglobin) Defect? (i) Sample characteristic of hemoglobin defect; (ii) Verify RBC morphology on slide. (i) Iron Deficiency? (i) Sample characteristic of iron

	deficiency anemia; (ii) Verify RBC morphology on slide. (3) The surveyor asked the laboratory manager if the laboratory had a policy for addressing flagged results. The laboratory manager stated to the surveyor, the laboratory followed the manufacturer's instructions for flagged results; (4) The surveyor then reviewed patient CBC result printouts from 3 months (January, June, and November 2018) and identified the laboratory failed to follow the manufacturer's instructions for the patient CBC results which obtained flags: (a) January 2018 - 26 of the 76 patient results reviewed, obtained flags. Examples included: (i) Patient #1: Tested 01/01/18 at 06:26 AM (aa) Immature Gran? flag obtained; (bb) There was no documentation a manual differential was performed. (ii) Patient #2: Tested 01/06/18 at 06:31 AM (aa) Immature Gran?, Left shift?, NRBC? flags obtained; (bb) There was no documentation a smear review or a manual differential was performed. (iii) Patient #3: Tested 01/18/18 at 13:56 PM (aa) NRBC? PLT Abn Distribution flags obtained; (bb) Although "Review smear" was documented on the printout, there was no documentation if NRBC's were identified; (cc) There was no documentation if platelet clumps were present and there was no documentation a platelet estimation was performed (The patient's platelet count result was 30). (b) June 2018 - 15 of the 44 patient results reviewed, obtained flags. Examples included: (i) Patient #4: Tested 06 /13/18 at 08:41 AM (aa) Immature Gran? flag obtained; (bb) There was no documentation a manual differential was performed. (i) Patient #5: Tested 06/15/18 at 15:11 PM (aa) Immature Gran?, Left shift?, NRBC? flags obtained; (bb) There was no documentation a smear review or a manual differential was performed. (iii) Patient #6: Tested on 06/26/18 at 12:00 AM (aa) Iron Deficiency? flag obtained; (bb) There was no documentation a smear review was performed to verify the RBC morphology. (iv) Patient #7: Tested on 06/28/18 at 14:40 PM (aa) Blasts? and HGB Defect? flags obtained; (bb) There was no documentation a smear review or a manual differential was performed. (c) November 2018 - 15 of the 33 patient results reviewed, obtained flags. Examples included: (i) Patient #8: Tested on 11/10/18 at 06:27 AM (aa) Atypical Lympho? flag obtained; (bb) Although a manual WBC differential was performed, there was no documentation if atypical lymphocytes were observed. (ii) Patient #9: Tested 11/27/18 at 16:59 PM (aa) Atypical Lympho? flag obtained; (bb) Although a manual WBC differential was performed, there was no documentation if atypical lymphocytes were observed (30 Lymphs were identified in the WBC differential). (5) The findings were reviewed with the laboratory manager who stated to the surveyor the laboratory failed to follow the manufacturer's instructions when patient CBC's results were flagged. NOTE: D5411 was cited on the previous recertification survey performed on 03/28/17-03/30/17.
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 laboratory manager, the laboratory failed to ensure the manufacturer's environmental

	specifications were met. Findings include: (1) On the first day of the survey, the laboratory manager stated to the surveyor the laboratory performed CBC (Complete Blood Count) testing (e.g. WBC (White Blood Count), RBC (Red Blood Count), Hematocrit, Hemoglobin, Platelet count, etc.) using the Sysmex XS-1000i hematology analyzer; (2) On the second day of the survey, the surveyor reviewed the manufacturer's environmental requirement. The manufacturer required a humidity between 30 and 85% for optimal performance. The surveyor reviewed the laboratory humidity/temperature records from 7 months (October 2017; January, February, March, April, August, and November 2018) and identified on 23 of the 213 days reviewed, the manufacturer's humidity requirement had not been met: (a) October 2017: On 3 of 31 days, the humidity was lower than 30%: (i) 25%: Day 27 (ii) 26%: Day 28 (iii) 29%: Day 29 (b) January 2018: On 8 of 31 days, the humidity was lower than 30%: (i) 20%: Day 5 (ii) 24%: Day 17 (iii) 25%: Days 4,12,24 (iv) 26%: Day 31 (v) 28%: Day 14 (vi) 29%: Day 25 (c) February 2018: On 6 of 28 days, the humidity was lower than 30%: (i) 24%: Days 2,3 (ii) 25%: Day 1 (iii) 26%: Days 4,25 (iv) 28%: Day 23 (d) March 2018: On 1 of 31 days, the humidity was lower than 30%: (i) 25%: Day 8 (e) April 2018: On 5 of 30 days, the humidity was lower than 30%: (i) 25%: Day 14 (ii) 26%: Days 8,9 (iii) 27%: Day 2 (iv) 29%: Day 5 (3) The surveyor reviewed the findings with the laboratory manager, who stated to the surveyor the laboratory failed to ensure the manufacturer's humidity requirement was met on the days listed above. NOTE: D5413 was cited at the previous recertification survey performed 03/28/17-03/30/17.
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, manufacturer's instructions, and interview with the laboratory manager, the laboratory failed to have control procedures that would detect immediate errors that would occur due to test system failure, adverse environmental conditions, and operator performance for chemistry testing. Findings include: (1) On the first day of the survey, the laboratory manager stated to the surveyor: (a) The laboratory performed chemistry testing (i.e., Albumin, Cholesterol, Chloride, CK (Creatinine Kinase), Glucose, Potassium, Sodium, Uric Acid, etc.) using the Ortho Vitros 350 analyzer; (b) Two levels (Level I and Level II) of Vitros Performance Verifier QC (Quality Control) materials were performed each day of patient testing for the analytes listed above. (2) The surveyor reviewed the manufacturer's assay sheet for the PV's (Performance Verifiers), which provided a lot specific range of means and SD (Standard Deviation) for each QC material and analyte. The laboratory manager stated to the surveyor the laboratory established its own mean, verified it was within the manufacturer's acceptable range of means, and used the manufacturer's

	SD's to determine the limits of acceptability for the control materials; (3) The surveyor then reviewed QC records (Levey Jennings graphs) for 8 analytes (Albumin, Chloride, Cholesterol, CK, Glucose, Potassium, Sodium, and Uric Acid) from 06/01 /17 through 12/11/18. The surveyor identified the laboratory utilized 6 QC lot numbers during the review period, as follows: (a) From 06/01/17 to 01/08/18: (i) PV I: Lot #N5113 (ii) PV II: Lot #P5115 (b) From 01/08/18 to 05/31/18: (i) PV I: Lot #Q5358 (ii) PV II: Lot #X5905 (c) From 05/30/18 through 12/11/18: (i) PV I: Lot #W5093 (ii) PV II: Lot #A6018 (4) During the review period, the Levey Jennings graphs for 1 of the 6 QC lot numbers used during the review period (PV II: Lot #A6018-Put into use 05/30/18) had no control outliers (approximately 1 out of every 20 control results should be defined as unacceptable and there were no results that were beyond the laboratory's established range). The surveyor identified the laboratory used SD's wider than the manufacturer's SD's listed on the assay sheet, as follows: (a) From 05/30/18 through 06/30/18: (i) Sodium: (aa) The SD listed on the assay sheet was 1.75 (bb) The SD used by the laboratory was 71.70 (b) From 05/30/18 through 10/31/18: (i) Chloride: (aa) The SD listed on the assay sheet was 1.4 (bb) The SD used by the laboratory was 54.5 (c) From 05/30/18 through 12/11/18: (i) Cholesterol: (aa) The SD listed on the assay sheet was 5.99 (bb) The SD used by the laboratory was 112.01 (ii) Glucose: (aa) The SD listed on the assay sheet was 4.72 (bb) The SD used by the laboratory was 135.60 (5) The surveyor reviewed the findings with the laboratory manager, who stated to the surveyor the manufacturer's provided SD had not been utilized for the above analytes. NOTE: D5441 was cited on the previous recertification survey performed 03/28/17-03/30/17.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on a review of records, policies and procedures, and interview with the laboratory manager, the laboratory failed to ensure units of blood were stored under appropriate conditions that included an adequate temperature alarm system that is regularly inspected. Findings include: ALARM CHECKS NOT PERFORMED (1) On the first day of the survey, the laboratory manager stated to the surveyor that units of packed red blood cells to be used for patient transfusions were stored in the Sanyo blood bank refrigerator; (2) On the second day of the survey, the laboratory manager stated to the surveyor the blood bank refrigerator alarm was checked quarterly for high /low activation; (3) The surveyor reviewed the refrigerator alarm check records from 04/01/17 through 12/12/18 and could not locate documentation that proved the alarm checks had been performed between 06/24/17 through 12/31/17 (Third and Fourth quarter of 2017); (4) The surveyor reviewed the records with the laboratory manager, who stated the alarm checks had not been performed quarterly as required in 2017. UNACCEPTABLE ALARM CHECKS (1) On the second day of the survey, the surveyor reviewed the laboratory's blood bank alarm check policy. It stated, "High alarm should sound before it reaches 6.0 degrees C" (Centigrade) "to be acceptable;" (2) The surveyor then reviewed the refrigerator alarm check records from 04/01/17

	through 12/12/18 and identified the First quarterly 2018 alarm check (performed on 03 /31/18) was unacceptable. The high temperature check activated the alarm at 6.7 degrees C instead of at 6.0 degrees C, which would allow units of packed red blood cells to be stored at an unacceptable temperature (packed red blood cells must be stored at 1-6 degrees Centigrade); (3) The surveyor reviewed the findings with the laboratory manager, who stated to the surveyor, the laboratory failed to follow its policy for ensuring units of packed red blood cells were stored at appropriate temperatures, as listed above. NOTE D5555 was cited at the previous recertification survey performed 03/28/17-03/30/17.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on review of records, manufacturer's instructions, and interview with the laboratory manager, the laboratory failed to take corrective action for unacceptable humidity results. Findings include: (1) On the first day of the survey, the laboratory manager stated to the surveyor the laboratory performed CBC (Complete Blood Count) testing (e.g. WBC (White Blood Count), RBC (Red Blood Count), Hematocrit, Hemoglobin, Platelet count, etc.) using the Sysmex XS-1000i hematology analyzer; (2) On the second day of the survey, the surveyor reviewed the manufacturer's environmental requirement. The manufacturer required a humidity between 30 and 85% for optimal performance. The surveyor reviewed the laboratory humidity /temperature records from 7 months (October 2017; January, February, March, April, August, and November 2018) and identified on 23 of the 213 days reviewed, the manufacturer's humidity requirement had not been met: (a) October 2017: (i) On 3 of 31 days, the humidity was lower than 30%: Days 27,28,29 (ii) There was no documentation corrective action (i.e. turn on humidifier, recheck humidity, etc.) had been taken for the unacceptable humidity. (b) January 2018: (i) On 8 of 31 days, the humidity was lower than 30%: Days 4,5,12,14,17,24,25,31 (ii) There was no documentation corrective action had been taken for the unacceptable humidity. (c) February 2018: (i) On 6 of 28 days, the humidity was lower than 30%: Days 1,2,3,4,23,25 (ii) There was no documentation corrective action had been taken for the unacceptable humidity. (d) March 2018: (i) On 1 of 31 days, the humidity was lower than 30%: Day 8 (ii) The corrective action was "turned on the humidifier." (e) April 2018: (i) On 5 of 30 days, the humidity was lower than 30%: Days 2,5,8,9,14 (ii) On day 14, the corrective action was "turned on the humidifier." (3) The surveyor reviewed the records again and could not find documentation which showed the humidity had been checked after the humidifier had been turned on, to ensure the manufacturer's required humidity was obtained; (4) The surveyor reviewed the findings with the laboratory manager, who stated to the surveyor there was no documentation available, which showed on the dates listed above, the laboratory took corrective action for unacceptable humidity results, and there was no documentation that proved that on the dates when corrective action had been taken, the manufacturer's requirement had been met.
D5787	TEST RECORDS CFR(s): 493.1283(a)

	The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory failed to maintain a record system that included the positive identification of patient specimens. Findings include: (1) On the first day of the survey, the laboratory manager stated to the surveyor: (a) CBC (Complete Blood Count) (e.g., WBC (White Blood Count), RBC (Red Blood Count), Hematocrit, Hemoglobin, Platelet count, etc.) testing was performed using the Sysmex XS-1000i analyzer; (b) The laboratory used the analyzer printout to record results of smear reviews and manual differentials. (2) On the second day of the survey, the surveyor reviewed patient CBC printouts from 3 months (January, June and November 2018). The surveyor identified the laboratory failed to include positive patient identification (i.e. name, unique patient identifier number, accession number, etc.) on the analyzer printouts of patient CBC's: (a) January 2018: There was no positive patient identification (e.g., name, accession number, etc.) documented on 26 of the 76 result printouts reviewed; (b) June 2018: There was no positive patient identification documented on 7 of the 44 result printouts reviewed; (c) November 2018: There was no positive patient identification documented on 11 of the 33 result printout reviewed. (3) The surveyor reviewed the findings with the laboratory manager and asked if there was a method to determine the patient identification from the result printout (i.e., sample number). The laboratory manager stated to the surveyor if the patient name or patient identification (medical record) number had not been entered into the analyzer, or written on the printout at the time of testing, there was no method to determine the patient identity from the result printouts.
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, manufacturer's instructions, written policies and procedures, and interview with the laboratory manager, the laboratory failed to have an ongoing mechanism for performing effective analytic quality assessment. Findings include: (1) It was determined the laboratory did not have an effective mechanism for performing analytic quality assessment due to the following issues identified during the survey: (a) The laboratory failed to ensure a policy had been approved, signed, and dated by the laboratory director before use. Refer to D5407; (b) The laboratory failed to ensure the manufacturer's instructions were followed. Refer to D5411; (c) The laboratory failed to ensure the manufacturer's environmental specifications were met. Refer to D5413; (d) The laboratory failed to have control procedures that detected

	immediate errors and monitored the accuracy and precision of the testing process. Refer to D5441; (e) The laboratory failed to ensure units of blood were stored under appropriate conditions. Refer to D5555; (f) The laboratory failed to take corrective action when the manufacturer's storage and operation requirements of analyzers and testing materials had not been met. Refer to D5785; (g) The laboratory failed to maintain a record system that included the positive identification of patient specimens throughout the testing process. Refer to D5787. NOTE: D5791 was cited on the previous recertification survey performed 03/28/17-03/30/17.
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 laboratory manager, 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 laboratory followed the manufacturer's instructions. Refer to D5411; (2) The laboratory failed to ensure the manufacturer's environmental specifications were met. Refer to D5413. NOTE: D6014 was cited on the previous recertification survey performed 03/28/17-03 /30/17.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on a review of records, and interview with the laboratory manager, the laboratory director failed to ensure proficiency testing samples were tested as required under Subpart H. Findings include: (1) On the first day of the survey, the surveyor reviewed 2017 and 2018 proficiency testing records. It was identified for 12 of the 16 events, the attestation statements had been signed approximately 1-3 months after the samples had been tested (not within a timeframe for the director to attest that, at the time of testing, the proficiency samples had been tested as required) as follows: (a) First 2017 Hematology/Coagulation Event: The samples were tested on 03/30/17 and the attestation statement had not been signed by the laboratory director until 04/24/17; (b) Second 2017 Immunology/ Immunohematology Event: The samples were tested on 08/10/17 and the attestation statement had not been signed by the laboratory

	director until 10/17/17; (c) Second 2017 Chemistry Event: The samples were tested on 05/30/17 and the attestation statement had not been signed by the laboratory director until 08/10/17; (d) Second 2017 Hematology/Coagulation Event: The samples were tested on 07/25/17 and the attestation statement had not been signed by the laboratory director until 08/22/17; (e) Third 2017 Hematology/Coagulation Event: The samples were tested on11/28/17 and the attestation statement had not been signed by the laboratory director until 01/03/18; (f) Third 2017 Immunology/Immunohematology Event: The samples were tested on 12/08/17 and the attestation statement had not been signed by the laboratory director until 03/01/18; (g) Third 2017 Chemistry Event: The samples were tested on 09/12/17 and the attestation statement had not been signed by the laboratory director until 10/17/17; (h) First 2018 Hematology /Coagulation Event: The samples were tested on 03/22/18 and the attestation statement had not been signed by the laboratory director until 05/30/18; (i) First 2018 Immunology/ Immunohematology Event: The samples were tested on 04/10/18 and the attestation statement had not been signed by the laboratory director until 05/30/18; (j) Second 2018 Chemistry Event: The samples were tested on 06/05/18 and the attestation statement had not been signed by the laboratory director until 08/07/18; (k) Second 2018 Hematology/Coagulation Event: The samples were tested on 07/26/18 and the attestation statement had not been signed by the laboratory director until 09/07 /18; (l) Second 2018 Immunology/Immunohematology Event: The samples were tested on 08/15/18 and the attestation statement had not been signed by the laboratory director until 09/07/18. (2) The surveyor reviewed the findings with the laboratory manager, and explained the attestation statement must be signed to definitively attest the proficiency samples were tested in the same manner as patient specimens. NOTE: D6016 was cited at the previous recertification survey performed 03/28/17-03/30/17.
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 laboratory manager, the laboratory director failed to ensure the laboratory had a quality control program which monitored the accuracy and precision of the complete analytic process. Findings include: (1) The laboratory director failed to ensure the laboratory had quality control procedures that detected immediate errors and monitored the accuracy and precision of the analytic process. Refer to D5441. NOTE: D6020 was cited at the previous recertification survey performed 03/28/17-03/30/17.
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, manufacturer's instructions, written policies and procedures, and interview with the laboratory manager, the laboratory director failed to ensure quality assessment programs were established and maintained to assure the quality of laboratory services provided. Findings include: (1) The laboratory director failed to ensure the laboratory had an effective quality assessment program due to the issues identified during the survey. Refer to D5791. NOTE: D6021 was cited at the previous recertification survey performed 03/28/17-03/30/17.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on a review of policies and procedures and interview with the laboratory manager, the laboratory director failed to specify in writing the responsibilities and duties of an interim laboratory manager. Findings include: (1) On the first day of the survey, the surveyor reviewed the Laboratory Personnel Report (Form CMS-209) completed by the laboratory prior to the survey and listed 6 individuals who performed moderate complexity testing: Laboratory manager, testing persons #1, #2, #3, #4, and #5; (2) The surveyor then reviewed records (e.g. proficiency testing, temperature/humidity, quality control, etc.) and identified an individual not listed on the Form CMS-209 who had reviewed records; (3) On the second day of the survey, the surveyor asked the laboratory manager when the individual was employed at the hospital and if the individual performed testing. The laboratory manager explained the individual did not perform testing but assisted in organizing the laboratory until the new laboratory manager was in place. The laboratory manager could not give specific dates when the individual served as the interim manager; (4) The surveyor then reviewed the laboratory's written policies and procedures. A written policy describing the responsibilities and duties of the interim laboratory manager could not be located; (5) The surveyor asked the laboratory manager if the duties and responsibilities of the interim laboratory manager had been specified in writing by the laboratory director. The laboratory manager stated a document written by the laboratory director, which listed a description of the interim laboratory manager's responsibilities and duties could not be located.