Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0959608	01/22/2018
Name of Provider or Supplier	**Street Address, City, State**	
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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
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on observation and interview with laboratory (lab) staff, the lab did not have safety data sheets for cleaning supplies and reagents used for patient testing, to ensure that if there was a spill or an exposure, lab staff would have information concerning the chemical spilled to remediate.
D5024	HEMATOLOGY CFR(s): 493.1215 If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493. 1281 through 493.1299. This CONDITION is not met as evidenced by: Based on review of hematology records and staff interview, it was determined that the lab failed to monitor temperature records (see D5413); failed to ensure control materials meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results (see D5481); failed to follow corrective action policies (see D5779); ensure patient test reports, printed from the hematology analyzer were maintained for at least two years (see D5789); and

	failed to ensure patient normal (reference values), for hematology testing were established (see D5807). The cumulative effect of these systemic problems resulted in the labs inability to ensure the accuracy and reliability of hematology testing.
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 review of the written procedure manual, temperature records, and interview with the testing person, the laboratory did not maintain documented temperature records for all areas of the laboratory each day of patient testing. Findings: A. 1. The laboratory did not document temperatures for the refrigerator where patient samples are stored when repeat testing is performed; 2. The refrigerator is located in the laboratory under the hematology analyzer. The testing person stated that sometimes samples are stores when problems happen and some patients have to be repeated; and 3. The testing person confirmed that temperatures were not taken each day of patient testing. B. 1. The laboratory did not document the room temperature and the humidity level each day of patient testing; 2. The analyzer operators manual states that analyzer operation temperature should be between 18-32 Degrees Celsius and 65-90 Degrees Fahrenheit and the optimal humidity level should be up to 95 percent; and 3. The testing person confirmed that room temperature and humidity level were not documented each day of patient testing.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: A. Based on record review and interview with laboratory (lab) staff, the lab did not ensure that quality control results met the laboratory's criteria for acceptability prior to reporting patient hematology resulta. Findings: 1. The maintenance procedure for the hematology analyzer states that quality control results must be within the range established by the manufacturer, to be acceptable and to continue with patient testing; 2. The lab tests three quality control reagents on the hematology analyzer. The labs written procedure requires results of each level (high, medium and low) be evaluated by the lab prior to patient testing; 3. The lab quality control records show that the lab accpeted quality control results that failed to meet the labs criteria for acceptability and performed patient testing; 4. On November 27, 2017 the result of the high level control for hemoglobin did not meet the lab's criteria for acceptability. The result of 18.8 was not within the manufacturer's established range of 17.2 to 18.6. Corrective

action was not taken; 5. On November 21, 2017 the result of the high level control for red blood count did not meet the lab's criteria for acceptability. The result of 5.89 was not within the manufacturers stated range of 5.46 to 5.86. Corrective action was not taken; 6. On September 26, 2017, two of the three hematology control reagents for white blood count were unacceptable. The results of both the high and normal levels of control did not meet the lab's criteria for acceptability. Corrective action was not taken. The control result for the high level white blood count control reagent was 18.2 and was not within the manufacturers stated range of 18.7 to 21.9. The control result for the normal level white blood count control reagent was 6.4 and was not within the manufacturers stated range of 6.8 to 8.4; 7. On May 15, 16 and 22, 2017 and June 2, 16 and 26, 2017, two of three hematology control reagents for hemoglobin were unacceptable. The results of both the high and normal levels of the hemoglobin control did not meet the lab's criteria for acceptability. Corrective action was not taken. On May15 the results of the high level of control was 19.1 and the normal level was 14.5. On May 16 the results of the high level of control was 19.1 and the normal level was 14.5. On May 22 the results of the high level of control was 19.0 and the normal level was 14.5. On June 2 the results of the high level of control was 19.1 and the normal level was 14.5. On June 16 the results of the high level of control was 18.9 and the normal level was 14.5. On June 26 the results of the high level of control was 19.2 and the normal level was 14.7. The manufacturer's stated range for the high level of the control for these lot numbers is 17.4 to 18.8 and the manufacturer's stated range for the normal level of the control is 13.2 to 14.4; 8. On May 15 and 16, 2017 the results of the high control for hemoglobin did not meet the lab's criteria for acceptability. Not only did the control fail on these individual days of testing, but also failed on consecutive dates of testing. Corrective action was not taken. The results of 19.1 obtained on both days did fall within the manufacturer's stated range of 17.4 to 18.8; 9. On May 19, 22, 23 and 25, 2017 the results of the high control for hemoglobin did not meet the lab's criteria for acceptability. Not only did the control fail on these individual days of testing but also failed on consecutive dates of testing. Corrective action was not taken. On May 19 the control result is 18.9, on May 22 the control result is 19.0, on May 23 the control result is 18.9 and on May 25 the control result is 18.9. The manufacturers acceptable range is 17.4 to 18.8; 10. On June 1, 2, 5 and 6, 2017, the results of the high control for hemoglobin did not meet the lab's criteria for acceptability. Not only did the control fail on these individual days of testing but also failed on consecutive days of testing. Corrective action was not taken. On June 1 the control result is 18.9, on June 2 the control result is 19.1, on on June 5 the control result is 19.1 and on June 6 the control result is 19.0 and retested as 19.3. The manufacturers acceptable range is 17.4 to 18.8; 11. On June 16, 19, 20, 22 and 26, 2017 the results of the high control for hemoglobin did not meet the lab's criteria for acceptability. Not only did the control fail on these individual days of testing but also failed on consecutive days of testing. Corrective action was not taken. On June 16 the control result is 18.9, on June 19 the control result is 18.9 on June 20 the control result is 19.2, on June 22 the control result is 19.0 and on june 26 the control result is retested as 19..2. The manufacturers acceptable range is 17.4 to 18.8; 12. On May 15 and 16, 2017 results of two of the three levels of hematology control reagents for the hemoglobin test did not meet the lab's criteria for acceptability and corrective action was not taken. Not only did the control fail on these individual days of testing but also failed on consecutive dates of testing. On May 15 and 16 the high level result was 19.1 and the normal was 14.5 each day. The manufacturer's acceptable range for the high control is 17.4 to 18.8 and the manufacturer's range for the normal level is 13.2 to 14.4; 13. On June 2, 2017 results of two of the three levels of hematology control reagents for the hemoglobin test did not meet the lab's criteria for acceptability and corrective action was not taken. On June 2 the high control result was 19.1 and the

manufacturer's acceptable range is 17.4 to 18.8 and the normal control was 14.5 and the manufacturer's acceptable range is 13.2 to 14.4; 14. On June 26 and 27, 2017 the results of the normal control for hemoglobin did not meet the lab's criteria for acceptability. Not only did the control fail on individual days of testing but also failed on consecutive days of testing. Corrective action was not taken. On June 26 the result was 14.7 and on June 27 the result was 14.6 and was retested, the retest result was 14.5. The manufacturer's acceptable range was 13.2 to 14.4; 15. On April 25, 27 and 28, 2017, the results of the high control for hemoglobin did not meet the lab's criteria for acceptability. Not only did the control fail on these individual days of testing but also failed on consecutive dates of testing. Corrective action was not taken. On April 25 the result was 18.8, On April 27 the result was 18.9 and on April 28 the result was 19.1. The manufacturer's acceptable range is 17.3 to 18.7. Also on April 27 and 28, 2017, the other two levels of control (normal and low also failed for the hemoglobin check, so all three levels of of the hemoglobin control were out of range on both these days. On April 27 the normal control result was 14.4 and on April 28 the normal control result was 14.4, the acceptable range was 12.9 to 14.1; On April 27, the low control result was 6.7 and on April 28 the low control result was 6.7, the acceptable range was 5.8 to 6.6; 16. On November 21, 2017 the result of the high level control for red cell count did not meet the lab's criteria for acceptability. Corrective action was not taken. The control result was 5.89 and the manufacturers acceptable range is 5.46 to 5.86; 17. On March 2, 2017 the high control result for white blood count did not meet the lab's criteria for acceptability. Corrective action was not taken. The control result was 18.0 and the manufacturer's acceptable range is 18.7 to 20.9; 18. On March 3, 2017 the high control for white blood cell count was tested three times, these results did not meet the lab's criteria for acceptability as each result 17.7, 18.5 and 18.3 did not meet the manufacturer's established range of 18.7 to 21.9; 19. On April 25, 2017 the high control result for hemoglobin is 18.8, and does not meet the labs criteria for acceptability, the manufacturer's acceptable range is 17.3-18.7. Corrective actions were not taken; 20. On March 7, 2017 the high, normal and low results for all three of the hematology platelet controls did not meet the labs criteria for acceptability and corrective actions were not taken. The high result was 427 with an acceptable range of 453 to 583, the normal result was 202 with an acceptable range of 223 to 303 and the low result was 102, with an acceptable range of 57 to 97; 21. On March 9, 10, 13 and 16, 2017 the results of testing the high level control for platelet counts did not meet the labs criteria for acceptability. Corrective actions were not taken, in addition the normal level of control also failed to meet the labs criteria for acceptability on March 13 and 16 so that on these two days two of three platelet control results were unacceptable and corrective action was not taken. On March 9 the high control was tested 3 times and the results 368, 372 and 351 did not meet the manufacturers acceptable range of 453 to 583 and on March 10, the lab obtained a result of 325 for the high control. On March 13 the high control result is 247 and on March 16 the high control result 232 and the acceptable range of the high control is 453 to 583. Also on March 13 the normal control result was 222 and on March 16 the normal control result was 210, the acceptable range is 223 to 303; 22. On all three consecutive days of testing for July 5, 6 and 7, 2016 the control results for the normal red blood count were 4.42 on each day, the acceptable range is 4.46 to 4.82. corrective actions were not taken; 23. On June 16, 2016 the result of the high level white blood count control was 22.7 acceptable range is 18.6 to 21.8 and corrective actions were not taken; 24. On June 27, 2016 the result of the high level white blood count control was 22.3 acceptable range is 18.6 to 21.8 and corrective actions were not taken; 25. On consecutive dates of testing the results of the high level white blood count reagent did not meet the labs criteria of acceptability and corrective actions were not taken. On June 20, 21 and 23, 2016 the control results were 22.0, 22.6 and 21.9, the acceptable

range is 18.6 to 21.8; 26. On consecutive dates of testing the high level results for the red blood count did not meet the labs criteria of acceptability and corrective actions were not taken. On June 13 and 14, 2016 the control results were 5.39 and 4.84, the acceptable range is 5.60 to 6.00, also on June 13 the normal red blood count control result of 4.20 with an acceptable range of 4.42 to 4.78 and the low control result of 2.20 with an acceptable range of 2.24 and 2.54 failed to meet the labs criteria for acceptability, all three control checks failed on this day and corrective actions were not taken; 27. On June 20 and 21, 2016 the high level results for the hemoglobin test did not meet the labs criteria of acceptability, these failures also occured on consecutive days and corrective actions were not taken. the results were 19.6 and 20.3 and the acceptable range is 17.7 to 19.1; 28. On June 3, 2016 the result of the high level platelet control was 627 acceptable range is 445 to 575 and corrective actions were not taken; 29. On June 6, 7, 8, 9, 10, 13 and 14, 2016 daily control results for the normal level of the red blood count did not meet the labs criteria for acceptability and in addition the failures occured on consecfutive days of testing. Corrective actions were not taken. The control results were 4.41, 4.39, 4.41, 4.41, 4.36, 4.20 3.88. The acceptable range is 4.42 to 4.78; 30. On June 29, 2016 the normal hemoglobin control did not meet the labs criteria for acceptability. The result 14.0 did not meet the acceptable range 12.7 to 13.9 and corrective actions were not taken; and 31. On June 16, 17 and 23, 2016 results of two of the three quality control reagents for hemoglobin failed to meet the labs criteria for acceptability and corrective action was not taken. The normal control results of 14.3 (obtained June 16), 14.0 (obtained June 17) and 14.1(obtained June 23) did not meet the acceptable range 12.7 to 13.9, In addition the high control results of 20.0 (obtained June 16), 19.7 (obtained June 17) and 20.3 (obtained June 23) did not meet the acceptable range 17.7 to 19.1. 30112 B. Based on review of the written procedure manual, review of hematology quality control (QC), and interview with the testing person, the laboratory did not maintain QC records when QC did not meet the laboratory's criteria of acceptability for hematology testing. Corrective action procedures were not docuemted when QC did not meet the laboratory's criteria of acceptability. Findings: 1 On 5/9/16 the high QC red blood cells (RBC) were low at 5.55 and not within the established normal reference range. A repeat of the QC was not performed; 2. On 5/9/16 the normal QC RBC's were low at 4.32 and not within the established normal reference range. A repeat of the QC was not performed; 3. On 5/24/16 the normal QC RBC's were low at 4.41 and not within the established normal reference range, upon repeat of normal QC the RBC's were still low 4.41 and not within the established normal reference range; 4. On 5/9/16 the low QC RBC's were out of range at 2.15 and not within the established normal reference range. A repeat of the QC was not performed; 5. On 5/23/16 the low QC RBC's were out of range at 2.21 and not within the established normal reference range. A repeat of the QC was not performed; 6. The RBC's were out of range with the high QC on 4/12/16 at 5.84, 4/13/16 at 5.88, 4/14/16 at 5.96, 4/18/16 at 5.90, 4/21 /16 at 5.85, and not within the established normal reference range. A repeat of the QC was not performed. on either date; 7. On 4/14/16 the high QC hematocrit was 53.2 and not within the established normal reference range. A repeat of the QC was not performed; 8. On 4/27/16 the high QC RBC's were low at 5.41 and not within the established normal reference range. A repeat of the QC was not performed; 9. on 4/28 /16 the high QC hemaglobin (HGB) was 19.1 and not within the established normal reference range. A repeat of the QC was not performed; 10. on 5/3/16 the high QC WBC's was 21.6 and the HGB was 19.9 and not within the established normal reference range. A repeat of the QC was not performed; 11. on 5/4/16 the high QC RBC's were low 5.42 and not within the established normal reference range. A repeat of the QC was not performed; 12. on 5/5/16 the high QC WBC's was 21.5 and the HGB was 19.7 and not within the established normal reference range. A repeat of the

	QC was not performed; 13. The RBC's were high with the normal QC on 4/12/ 16 at 4.84 and on 4/18/16 at 4.83 and not within the established normal reference range. A repeat of the QC was not performed. on either date; 14. The HGB was high with the normal QC on 4/25/16 at 14.4, 4/26/16 at 14.2 , 4/28/16 at 14.2 , 5/3/16 at 14.4 , 5/4 /16 at 14.3 , and not within the established normal reference range. A repeat of the QC was not performed. on either date; 15. The platelets were high with the low QC on 4 /13/16 at 109 and 4/22/16 at 102, and not within the established normal reference range. A repeat of the QC was not performed. on either date; 16. The lymphocytes were high with the normal QC on 4/4/16 at 2.9 , 4/5/16 at 2.9 , 4/7/16 at 2.9, and not within the established normal reference range. A repeat of the QC was not performed. on either date; and 17. The granulocytes with the high QC on 5/3/16 was 17.3 and on 5 /5/16 was 17.2 and not within the established normal reference range. A repeat of the QC was not performed. on either date.
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. This STANDARD is not met as evidenced by: Based on record review and interview with laboratory (lab) staff, the hematology lab did not follow corrective action policies. Findings: 1. The hematology written procedure states that staff are to document problems, including quality control failures and corrective actions on the "Remedial Action Log"; 2. The lab did not complete the "Remedial Action Log" and did not have any entries for 2016 and 2017; 3. On March 20, 2017, The lab had service performed on the hematology analyzer because "... plt on start up not passing and dollar signs on WBC patient samples", as reported on the service record problem description. The problem and the corrective actions was not reported on the "Remedial Action Log"; 4. Hematology controls failed to meet the labs criteria for acceptability and the "Remedial Action Log" was not completed. See D5481 for findings; and 5. This was confirmed during interview of lab staff on the day of survey.
D5789	TEST RECORDS CFR(s): 493.1283(b) Records of patient testing including, if applicable, instrument printouts, must be retained. This STANDARD is not met as evidenced by: Based on record review and interview with laboratory (lab) staff, the lab did not ensure patient test reports, printed from the hematology analyzer were maintained for at least two years. Findings: 1. The hematology analyzer printed the patient test report, this report is used as both an intermediate record and final patient report; 2. The laboratory did not maintain final reports printed from the hematology analyzer, the report were transcribed into the electronic medical record and then discarded, unless the provider requested a copy of the report; and 3. This was confirmed with staff, during interview on the day of survey.

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 record review and interview with laboratory (lab) staff, the lab did not ensure patient normal (reference values), for hematology testing, were established. Findings: 1. The labs written procedure did not include normal patient ranges for hematology testing; 2. The normal patient ranges on the hematology report printed from the analyzer were different than the normal patient ranges in the electronic medical record; and 3. This was confirmed with lab staff during interview on the day of survey.
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 hematology records and staff interview, it was determined that the lab director failed to maintain duties and responsibilities for all persons involved with laboratory testing (See D 6004); failed to failed to maintain the quality assurance (QA) program for the overall acceptability of laboratory services (See D 6021); did not ensure that hematology testing quality control programs are maintained (See D 6022); and did not ensure remedial actions were taken when quality control testing for hematology failed to meet the labs criteria for acceptability (see D 6024). The cumulative effect of these systemic problems resulted in the lab directors inability to ensure the accuracy and reliability of hematology testing.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of the written procedure manual and interview with the testing person, the laboratory director failed to maintain duties and responsibilities for all

	persons involved with laboratory testing. Findings: 1. The laboratory director did not have written duties and responsibilities for the laboratory director and the testing person involved in performing hematology testing; and 2. The testing person confirmed that duties and responsibilities were not in the procedure manual for the laboratory director and the testing person.
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 the written procedure manual, review of quality assurance records, and interview with the testing person, the laboratory director failed to maintain the quality assurance (QA) program for the overall acceptability of laboratory services. Findings: 1. The laboratory director did not perform monthly QA checks on the "monthly quality assurance checklist" when performing hematology testing; 2. The "monthly quality assurance checklist" for laboratory services that included laboratory safety, personnel policies, proficiency testing, patient test management, quality control, and quality assurance had predetermined answers of "YES" in the YES/NO box for all laboratory areas and signed annually by the laboratory director for the years 2016 and 2017; 3. The laboratory director and the testing person documented on the "monthly quality assurance checklist" the date and initials at the bottom of the checklist each month during the year 2016 and 2017 and the predetermined answers of "YES" in the YES/NO box for all laboratory areas were not changed when instrument and quality control problems occurred when patient testing was performed; and 4. The testing person stated that she and the laboratory director would review the "monthly quality assurance checklist" but the "YES" in the YES/NO box for all laboratory areas were not changed due to instrument and quality control problems the occurred when patient testing was performed and the laboratory director signed the QA checklist once annually.
D6022	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on record review and interview with laboratory (lab) staff, the lab director did not ensure that hematology testing quality control programs are maintained. Findings: 1. The labs written procedures state that the lab will perform parallel quality control

	checks on hematology control reagents; 2. Parallel checks ensure that the lab verifies that a new lot of quality control reagents performs as expected prior to being placed into use. The new lot of control is tested in parallel with the expiring lot of reagent, and the results of the new lot are checked with the manufacturers expected ranges for the new lot; 3. Lab staff stated that parallel checks were not performed; and 4. This was confirmed during interview with lab staff on the day of survey.
D6024	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) 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)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, This STANDARD is not met as evidenced by: Based on record review and interview with lab staff, the director did not ensure remedial actions were taken when quality control testing for hematology failed to meet the labs criteria for acceptability. Findings: 1. The director did not ensure that the hematology lab followed it's written corrective action policies; and 2. See D5481 and D5779 for findings.