Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2144799	06/27/2019
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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on record review, the laboratory did not have a written procedure in place to identify the person performing quality control testing for hematology. Findings: 1. The lab performs hematology testing on an automated analyzer and reports a complete blood count with automated differential (CBC), the lab retains the daily quality control printouts and keeps a quality control review log that is a monthly record of quality control testing; 2. Ten of ten printed quality control reports reviewed for May

	2019 did not have initials of the testing person recorded on the patient reports and the identity of the testing person was not documented in the monthly quality control review logs for both May 2019 and June 2019.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review, the laboratory (lab) did not have written procedures to verify the performance of a new lot of hematology quality control reagent in parallel with the existing control prior to switching to the new lot of quality control reagent; findings: 1. The lab performs quality control testing using an assayed control; and 2. The lab did not have a written procedure to verify a new lot of quality control reagent by testing it in parallel with the old lot of quality control reagent and verifying that the quality control results meet the values reported by the manufacturer.
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 record review, the laboratory did not have a written procedure in place to identify the person performing patient testing for hematology. Findings: 1. The lab performs hematology testing on an automated analyzer and reports a complete blood count with automated differential (CBC), the patient report from the analyzer is scanned into the patient medical record; and 2. Ten of Ten printed patient test reports reviewed for May 2019 did not have initials of the testing person recorded on the patient reports.
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 record review, the laboratory (lab) director did not ensure that the quality assurance program was maintained to assure quality of lab services. Findings: 1. The laboratory completes a monthly checklist to track lab performance; and 2. From June 2018 thru May 2019 (each month) the lab reported that proficiency Test samples were tested exactly like patient samples even though the lab only participated in 3 proficiency test events during that 11 month span and this observation should only be documented on 3 months of records.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: A. Based on record review, the laboratory (lab) director acting as technical consultant did not establish hematology quality control procedures to ensure acceptable levels of analytical performance. Findings: 1. The lab tests three levels of hematology quality control reagents, low, normal and high, these reagents are assayed by the manufacturer who publishes the target values and the acceptable ranges for every analyte for each level of control; 2. The lab did not have written procedures to identify that second (or more) consecutive failures of an analyte (the test result fails to come within the manufacturer's assayed value after retesting or testing the next day) require corrective action prior to patient testing; 3. The lab did not identify quality control failures and take corrective actions prior to patient testing when control results failed to come within the manufacturer's assayed value after retesting or testing the next day (consecutive test events); 4. On January 31, 2019 and January 30, 2019 the high platelet count quality control results did not meet the manufacturer's assayed limits on two and three consecutive days of testing. On January 29, 2019 the laboratory obtained a result of 456 (manufacturer's assayed limits 382 +/- 60) and on January 30, 2019 the laboratory obtained a result of 445 and on January 31, 2019 the laboratory obtained a result of 454. Corrective action was not taken to resolve the quality control failure prior to testing patient samples; 5. On August 31, 2018 the low platelet count quality control result did not meet the manufacturer's assayed limits on two consecutive days of testing. On August 30, 2018 the laboratory obtained a result of 98 (manufacturer's assayed limits 77 +/- 20) and on August 31, 2018 the laboratory obtained a result of 99. Corrective action was not taken to resolve the quality control failure prior to testing patient samples; 6. On June 28, 2018 the high red blood cell count and high hematocrit quality control results did not meet the manufacturer's assayed limits on two consecutive day of testing. On June 27, 2018 the laboratory

	obtained a result of 4.82 for the red blood cell count (manufacturer's assayed limits for red blood cell count 5.26 +/- 0.30) and 44.2 % for the hematocrit (manufacturer's assayed limits for hematocrit 48.5 +/- 4) and on June 28, 2018 the laboratory obtained a result of 4.77 for the red blood cell count and 43.4 for the hematocrit. Corrective action was not taken to resolve the quality control failure prior to testing patient samples; 7. On June 29, 2018 the normal platelet count quality control result did not meet the manufacturer's assayed limits on two consecutive days of testing. On June 28, 2018 the laboratory obtained a result of 275 (manufacturer's assayed limits 219 +/- 40) and on June 29, 2018 the laboratory obtained a result of 274. Corrective action was not taken to resolve the quality control failure prior to testing patient samples; and 8. On June 26, 2018 the low platelet count quality control result did not meet the manufacturer's assayed limits on two consecutive days of testing. On June 25, 2018 the laboratory obtained a result of 107 (manufacturer's assayed limits 83 +/- 20) and on June 26, 2018 the laboratory obtained a result of 107. Corrective action was not taken to resolve the quality control failure prior to testing patient samples. B. Based on record review, the laboratory director did not have written procedures in place to identify hematology quality control failures when control results failed to meet the manufacturer's acceptable range by greater than three standard deviation from the mean value for that analyte. Findings: 1. The lab tests three hematology quality control reagents (low, normal and high). these reagents are assayed by the manufacturer who publishes the target values and the acceptable ranges for every analyte for each level of control; and 2. The laboratory written procedure did not have instructions for identifying a single analyte failure due to a test result that was greater than three standard deviations from the mean value and taking corrective action.
D6044	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(6) (b) The technical consultant is responsible for-- (b)(6) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly; This STANDARD is not met as evidenced by: Based on record review, the laboratory (lab) director acting as technical consultant did not ensure that corrective actions were taken when hematology quality control results failed to meet the laboratory's criteria for acceptability. Findings: 1. The lab tests three levels of hematology quality control reagents, low, normal and high, these reagents are assayed by the manufacturer who publishes the target values and the acceptable ranges for every analyte for each level of control; 2. The laboratory's written procedure states that hematology control results fail to meet the laboratory's criteria for acceptability when 2 or more control results do not come within the manufacturer's assayed range for that analyte; 3. On January 31, 2019 both the high and low control results for the platelet count failed to meet the laboratory's criteria for acceptability. The high reagent control result was 454 (manufacturer's assayed limits 382 +/- 60) and the low reagent control result was 103 (manufacturer's assayed limits 79 +/- 20). Corrective action was not taken to resolve the quality control failure prior to testing patient samples; 4. On January 29, 2019 both the high and low control results for the platelet count failed to meet the laboratory's criteria for acceptability. The high reagent control result was 456 (manufacturer's assayed limits 382 +/- 60) and the low reagent control result was 105 (manufacturer's assayed limits 79 +/- 20). Corrective action was not taken to resolve the quality control failure prior to testing patient samples; and 5. On June 27, 2018 both the high and normal control results for the red

	blood cell count failed to meet the laboratory's criteria for acceptability. The high reagent control result was 4.82 (manufacturer's assayed limits 5.26 +/- 0.30) and the normal reagent control result was 3.80 (manufacturer's assayed limits 4.11 +/- 0.25). Corrective action was not taken to resolve the quality control failure prior to testing patient samples.