Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1023959	01/22/2018
Name of Provider or Supplier	**Street Address, City, State**	
Carlos A Regalado Md Pa	2121 E Griffin Pwy Suite 1, Mission, TX	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
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 review of laboratory policy, review of manufacturer's instructions, patient reports, and confirmed in interview of facility personnel, the laboratory failed to provide documentation of a policy to resolve flags on CBC (complete blood count) results prior to their release to the healthcare provider. The findings were: 1. Review of the laboratory's policy, "Plan for Correction/Prevent CBC Flags (Numbers, Letters, and Dots: *):" on 01/22/2018, stated, " ...It will be decision of MD or lab director to run again the CBC with left sample or send the patient to other lab for repeating CBC or report only not affected values on the patient's chart." 2. Review of the

	manufacturer's instructions for the Beckman Coulter Act Diff 2 hematology analyzer (PN: 4237495B, June 2003), stated, "1, 2, 3, 4, M: Verify results according to your laboratory's protocol." 3. Random review of patient results from January 2018 revealed the following patients had CBC results with flags that were not verified prior to their release to the healthcare provider: ID: 000001779 Date: 01/16/2018 Flag(s): 3 ID: 000001798 Date: 01/19/2018 Flag(s): 2 4. The laboratory was asked to provide documentation of a policy that would instruct testing personnel on how to resolve CBC results with flags prior to their release to the healthcare provider. No documentation was provided. 5. An interview with testing personnel 1 (as listed on Form CMS-209) on 01/22/2018 at 1527 hours in the break room confirmed the findings. She revealed that the laboratory repeats the CBC and then shows the Dr. and he decides what follow-up to perform.
D5459	CONTROL PROCEDURES CFR(s): 493.1256(d)(5)(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--Each electrophoretic procedure include, concurrent with patient specimens, at least one control material containing the substances being identified or measured. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory quality control records and confirmed in interview of facility personnel, the laboratory failed to provide documentation of verifying the acceptability of new lots of hematology controls before being placed into use. The findings include: 1. A review of the laboratory's quality control records from January 2016 to December 2017 revealed the laboratory failed to verify the acceptability of the following lot numbers: Lot 088800 (current lot) Lot 078800 (current lot) Lot 068800 (current lot) Expiration Date: 04-09-2018 Lot 088000 Lot 078000 Lot 068000 Expiration Date: 01-01-2018 Lot 089900 Lot 079900 Lot 069900 Expiration Date: 10-09-2017 Lot 069300 Lot 079300 Lot 089300 Expiration Date: 07-17-2017 2. The laboratory was asked to provide documentation of running the new lots of controls concurrently with an established and verified control lot in order to verify the new quality control values. No documentation was provided. 3. An interview with testing personnel one (as listed on Form CMS-209) on 01/22/2018 at 1558 hours confirmed the findings. . Key: CMS - Centers for Medicare and Medicaid Services