Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0226355	03/06/2018
Name of Provider or Supplier	**Street Address, City, State**	
Brandermill Pediatric & Adolescent Medicine	4902 Millridge Pky, Midlothian, VA	

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	An announced CLIA recertification survey was conducted at Brandermill Pediatric and Adolescent Medicine on March 6, 2018 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
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 a laboratory tour, review of the procedure manual, hematology analyzer manufacturer's user guide, and an interview, the laboratory did not have a written policy or a protocol for patient complete blood count (CBC) critical value results

	assayed on the QBC STAR hematology analyzer from February 2016 through the date of the survey on March 6, 2018. Findings include: 1. During a laboratory tour at approximately 10:30 AM on 3/6/18, the inspectors noted that the laboratory had patient reference ranges posted on the cabinet above their Drucker Diagnostics QBC STAR hematology analyzer. The inspectors asked the primary testing personnel how CBC results are placed into the patient records and if critical values were established. The testing personnel stated "We print results from the instrument and show to the doctor. We place one copy of the results in our test log and one copy in the patient chart. We do not have critical values posted. I do not think we have critical values formally established." 2. Review of the laboratory's procedure manual revealed no written critical value policy or protocol for CBC critical (panic) value results assayed on the QBC STAR hematology analyzer. 3. Review of the Drucker Diagnostics user's guide revealed instructions on page eighteen (18) to "establish your laboratory's panic values and write them in your policy". The inspectors requested to review the established panic values. No documentation was available for review. 4. In an interview with the primary testing personnel at approximately 12:00 PM on 3/6/18, it was confirmed that the laboratory did not have a written policy or a protocol for patient CBC critical value results included in their procedure for the QBC STAR.