

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0859009	(X3) Date Survey Completed 12/10/2019
Name of Provider or Supplier Vcu Health Tanglewood Family Medicine	Street Address, City, State 9782 Hwy 903, Bracey, 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 VCU Health Tanglewood Family Medicine on December 10, 2019 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:
D5469	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of policies and procedures, quality control (QC) records, lack of documentation, and interviews, the laboratory failed to perform evaluations to verify seven (7) of 7 new lot numbers of hematology QC materials used for monitoring the accuracy of patient complete blood count (CBC) testing during the twenty-one (21) months reviewed. Findings include: 1. Review of the laboratory's procedure manual revealed no Medonic CA620 hematology instrument procedure for verification of new lot numbers of Medonic Boule QC assayed ranges. 2. Review of the Medonic QC records from 3/1/18 to 12/10/19 revealed the following 7 Medonic Boule QC lot</p>

numbers were utilized to monitor patient CBC test results analyzed on the laboratory's CA620 instrument: 21802, 21805, 21808, 21811, 21902, 21905, 21908. The inspector requested to review documentation that each of the QC lot numbers outlined above were confirmed (verified). No documentation was available. The lead testing personnel stated at approximately 11:30 AM: "The Medonic field service technician has mentioned to us that we should be doing the lot to lot verification. We plan to reach out to the hospital point of care coordinator for the procedure". 3. In an exit interview with the lead testing personnel at 12:30 PM, the above findings were confirmed.