

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0227198	(X3) Date Survey Completed 10/16/2019
Name of Provider or Supplier Vernon J Harris Eeche DbA	Street Address, City, State 5855 Bremo Road Suite 302, Richmond, 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 the laboratory of Dr.'s Meyer, Day, and Lovings, PC on October 16, 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:
D5437	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.</p> <p>This STANDARD is not met as evidenced by: Based on review of policies and procedures, hematology calibration records, and an interview, the laboratory failed to document Beckman Coulter AcTdiff calibration procedures every six months for Complete Blood Count (CBC) patient testing according to their written procedure in calendar year 2018. Findings include: 1. Review of the laboratory's Quality Assurance (QA) procedure manual revealed a "CBC Calibration" policy that stated "calibration frequency for Beckman Coulter AcTdiff CBC is at least once every six (6) months". 2. Review of the AcTdiff instrument calibration documentation from January 2018 to the date of the inspection on 10/17/19, a total of twenty-two (22) months, revealed the following calibration records: 03/14/18, 11/03/18, and 04/20/19. The inspector requested to review</p>

additional calibration records for the AcTdiff analyzer during the timeframe of 09/14/18 to 11/03/18. No additional calibration documentation was available for review. The lead testing personnel stated at, approximately 2:00 PM, "We did miss the deadline for the calibration in that time period. I do not recall why it was missed." 3. In an interview with the lead testing personnel at approximately 3:30 PM, the above findings were confirmed.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:
Based on review of policies and procedures, Quality Control (QC) records, and an interview, the laboratory failed to establish and follow a written policy for QC statistics review in order to monitor, assess and correct problems with their hematology analyzer for twenty-one (21) of the twenty-two (22) months reviewed. Findings include: 1. Review of the laboratory's policies and procedures revealed no quality assurance plan to review, monitor, assess and correct QC statistical concerns with their Beckman Coulter AcTdiff analyzer. 2. Review of QC records from January 2018 through September 2019 (timeframe of 22 months) revealed a lab director review sheet with director signature indicating monthly QC statistics record review for November 2018 (dated 12/14/18). The inspector requested to review additional hematology QC statistics review. No records were available. The lead testing personnel stated, at approximately 3:00 PM, "I print the QC daily log and look at it to make sure we have not missed any QC. I do not look at the statistic data or print the graphs routinely. I can ask our LD to review the charts monthly going forward". 3. In an interview with the lead testing personnel at approximately 3:30 PM, the above findings were confirmed.