Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0227198	03/02/2022
Name of Provider or Supplier	**Street Address, City, State**	
Vernon J Harris Eechc Dba	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 Drs Meyer, Day and Loving, PC on 03/02/22 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: The laboratory is performing COVID-19 testing and is in compliance with the applicable COVID-19 reporting requirements.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) 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. This STANDARD is not met as evidenced by: **REPEAT DEFICIENCY** Based on review of policy and procedures (P&P), calibration records, lack of documentation, and interview, the lab failed to follow the established P&P for performing the calibration procedures every six months on the hematology analyzer for 12 of 12 months reviewed. Findings include: 1. Tour of the lab testing area on 03/02/22 at approximately 09:30 AM revealed the lab utilizes the Beckman Coulter AcTDiff hematology analyzer to perform Complete Blood Count (CBC) patient testing. 2. Review of the P&P revealed a "CBC Calibration" policy that stated, "Calibration frequency for Beckman Coulter AcTDiff CBC is as least once

	every six months." 3. Review of calibration records revealed documentation of calibration procedures on 04/22/20 and 03/27/21. There was lack of documentation of calibration procedures between the specified dates. Additional documentation was not available for review upon request. 4. An exit interview with the lab director and testing personnel on 03/02/22 at approximately 1200 confirmed the findings.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on review of policy and procedures (P&P), the Laboratory Personnel Report Form (CLIA) (CMS-209 Form), testing personnel (TP) records, lack of documentation and interview, the lab director failed to follow the established P&P for performing annual competency assessments for three of three TP in 2019, 2020 and 2021. Findings include: 1. Review of P&P revealed the following statements, "Quality Assurance Plan 6. Personnel Assessment- At least annually, the laboratory director and /or technical consultant will review the performance of each employee working in the laboratory to assure employee competency. The written result of the review will be filled in the individual's personnel file." 2. Review of the CLIA CMS 209 form revealed there are three TP (TP A, B and C). See attached Testing Personnel code sheet. 3. Review of TP records revealed lack of documentation of annual competency assessments for TP A, B and C in 2019, 2020 and 2021. The surveyor requested to review annual competency assessment documentation and there were no documents available for review. 4. An exit interview with the lab director and testing personnel on 03/02/22 at approximately 1200 confirmed the findings.