

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0232914	(X3) Date Survey Completed 07/24/2019
Name of Provider or Supplier Chp-Cvfp - Internal Medicine	Street Address, City, State 2215 Landover Place, Lynchburg, 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 Initial survey was conducted at the CVFP Internal Medicine on July 24, 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:
D5445	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on the entrance tour of the laboratory, review of policy and procedures (P&P), quality control (QC) records, lack of documentation, patient data logs, and interviews with the lab supervisor and testing personnel (TP), the laboratory failed to follow the established Individualized Quality Control Plan (IQCP) for performing external QC materials every 30 days for the Troponin I, Creatine kinase-MB (CK-MB), D-Dimer, Myoglobin and brain natriuretic peptide (BNP) analytes from March 30, 2019 to May 9, 2019 and reporting twenty-two (22) patients. Findings include: 1. Entrance tour of the laboratory at approximately 9:45 AM revealed that the lab utilizes three (3) Alere Triage Meters (Serial Numbers 75282, 75266, and 68929) to assay patient samples for Troponin I, CK-MB, D-Dimer, Myoglobin and BNP analytes. 2. Review of the P&P revealed an established IQCP (signed by the lab director on 12/30/2015 and by the new lab director on 02/05/2019) that included the following statements: "Triage</p>

Shortness of Breath Panel for the Troponin I, CK-MB, D-Dimer, Myoglobin and BNP analytes" "Quality Control- IQCP is utilized with this test system to perform QC as required to satisfy the manufacturer and individual lab needs. External liquid QC is performed with each new lot of reagent and/or shipment and every 30 days. External electronic QC is performed daily to ensure that the meter is functioning properly. Each meter is set to lock out patient testing if the Electronic QC is not performed daily and External Liquid QC is not performed every 30 days." 3. Review of the external QC records from October 1, 2018 and up to June 30, 2019 revealed external QC performed on 02/28/19 and on May 10, 2019 and the lack of documentation of performance of external QC between those dates. An interview with the lab supervisor at approximately 2:30 PM revealed that according to the current IQCP for the test system, the laboratory was to perform external QC assays on March 30, 2019 and April 29, 2019. The inspector requested to review documentation of external QC for timeframe specified. There was no documentation available for review. The inspector asked the lab supervisor and testing personnel to demonstrate if the 3 meters were set to lock out patient testing as specified in the IQCP. No meters had the lock out function enabled. 4. Review of the LabDaq Laboratory Information System (LIS) revealed that 22 patients assayed for the Troponin I, CK-MB, D-Dimer, Myoglobin and BNP analytes for the above-specified timeframe. 5. An interview with the lab supervisor and testing personnel at approximately 4:15 PM confirmed the findings.