Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D1032460	12/04/2018
Name of Provider or Supplier	**Street Address, City, State**	
Cvfp-Walk In-Amherst	816 S Main Street, Amherst, 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 Physicians Treatment Center of Amherst on December 4, 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:
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on the review of proficiency testing (PT) records and interview, the testing personnel (TP) failed to sign three (3) of the three (3) attestation statements reviewed. Findings include: 1. Review of the American Proficiency Institute (API) hematology PT records for all two (2) events in 2017 and one (1) event in 2018 revealed a lack of the TP signature on the attestation statements for the following: 2017 Event B, 2017 Event C, 2018 Event A. 2. An interview with the primary TP and lab consultant at approximately 12:00 PM confirmed the findings.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing

	samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on the review of proficiency testing (PT) records and interview, the laboratory failed to maintain the original Complete Blood Count (CBC) test records for three (3) of the three (3) events reviewed. Findings include: 1. Review of the American Proficiency Institute (API) hematology PT records for the two (2) events in 2017 and one (1) event in 2018 revealed no original CBC testing records for the following events: 2017 Event B, 2017 Event C, 2018 Event A. 2. An interview with the primary testing personnel and lab consultant at approximately 12:00 PM confirmed the findings.
D2123	HEMATOLOGY CFR(s): 493.851(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on the review of proficiency testing (PT) records and interview, the laboratory failed to participate in one (1) of the four (4) Complete Blood Count (CBC) module events reviewed. Record review included 2017 and 2018 testing events. Findings include: 1. Review of the CASPER 096 Laboratory Application and Survey Summary Report and the American Proficiency Institute (API) PT records revealed the laboratory received a score of 0% for the 2018 Event B CBC module due to a failure to participate. 2. An interview with the primary testing personnel and lab consultant at approximately 12:00 PM confirmed the above-listed findings.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of the manufacturer operator's guide, policy/procedures, hematology

	records, quality assurance (QA) records, testing personnel (TP) records and interviews, the laboratory failed to 1) follow manufacturer's instructions for performing instrument calibrations (Cross Reference D5437); and 2) follow the established QA policy (Cross Reference D5791). **Repeat deficiencies.
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: Based on review of the manufacturer operator's guide, instrument calibration records, and interview, the laboratory failed to follow manufacturer's instructions for the performance of calibration procedures at least once every six (6) months in calendar year 2018. Findings include: 1. Review of the Beckman Coulter Operator's guide- 5.1 Calibration procedures reveals that the laboratory testing personnel are to perform calibration procedures at least once every six (6) months. 2. Review of the calibration records for the instrument revealed calibration performed on May 24, 2017 and September 20, 2017. Calibration documentation was not available for review for the calendar year 2018. 3. An interview with the lab consultant at approximately 12:00 PM confirmed the above-listed findings. *This is a repeat deficiency.
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 policy/procedures, hematology records, quality assurance (QA) records, testing personnel (TP) records and interviews, the laboratory failed to follow the established QA policy from June 1, 2017 and up to the date of survey on December 4, 2018. Findings include: 1. Review of the QA policy (signed by the lab director 11/28/2016) revealed the following statements: " Three major phases of laboratory testing evaluated are as follows: 1. Pre-analytical a. Specimen collection b. Storage and processing c. Personnel training 2. Analytical a. Quality control b. Preventative maintenance c. Calibrations and calibration verifications 3. Post-analytical a. Result reporting b. Turn-around times Implementation of a Quality Assessment Program: the major processes to be evaluated are organized by month. The frequency of QA reviews will vary depending on the area of review. Areas that

	are particularly problematic or have a greater potential to affect the quality of patient test results will be reviewed at a greater frequency. A problem log will be utilized to enable visual recognition of patterns and trends. Monthly checklists are provided for each of these reviews." 2. Review the hematology records from June 1, 2017 and up to the date of survey revealed no documentation of the monthly checklists. Documentation of the review of QC records was not available for review. 3. Review of the instrument calibration records revealed no documentation of the performance of the required 6-month calibration in 2018 (Cross Reference D5437). 4. Review of personnel records revealed no documentation of training or competency assessments performed for 2 new TP in 2017 and 2018 (Cross Reference D6029). 5. An interview with the primary TP and lab consultant at approximately 12:00 PM confirmed the above-listed findings. **Repeat deficiency.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of the manufacturer operator's guide, policy/procedures, hematology records, quality assurance (QA) records, testing personnel (TP) records and interviews, the laboratory director failed to 1) follow the established QA policy (Cross Reference D6021); and 2) ensure TP received training and perform competency assessments prior to patient testing in 2017 and 2018 (Cross Reference D6029).
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of policy/procedures, hematology records, quality assurance (QA) records, testing personnel (TP) records and interviews, the laboratory director failed to follow the established QA policy from June 1, 2017 and up to the date of survey on December 4, 2018. (Cross Reference D5791).
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel

	have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on the review of the Laboratory Personnel Report Form (CLIA) (CMS-209 Form), testing personnel (TP) records and interviews, the laboratory director failed to ensure that two (2) of two (2) new TP had documented training and competency assessments prior to performing patient testing procedures for hematology from November 15, 2017 and up to the date of survey on December 4, 2018. Findings include: 1. Review of CLIA CMS-209 form revealed that TP A and TP B were new TP (See attached TP Code Sheet). 2. Review of TP records and an interview with the lab consultant at approximately 10:30 AM revealed that just prior to on-site survey, the training and competency assessment documents for TP A and TP B were completed. There was no documentation of training or competency assessments prior to patient testing procedures by the laboratory director for the following TP: TP A- hired and performing testing November 15, 2017; TP B- hired and performing testing July 9, 2018. 3. An interview with the lab consultant and primary TP at approximately 12:00 PM confirmed the above-listed findings.