Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D1032460	03/09/2021
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 on-site survey was conducted at the Physicians Treatment Center of Amherst on March 9, 2021 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. The initial contact and entrance interview with laboratory conducted on February 22, 2021 with off-site record review of documentation and a follow-up email on March 4, 2021. Specific deficiencies cited are as follows: The laboratory was not in compliance with the following 42 CFR part 493 CLIA Regulations: D2000 - 42 C.F.R. 493-801 Condition: Enrollment and Testing of Samples.
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on review of proficiency testing (PT) records and interviews, the laboratory failed to enroll in a hematology PT complete blood count (CBC) module for the first and second events in 2019. (Cross Reference D 2123.)
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, lack of documentation, and interviews, the lab failed to enroll in a hematology PT complete blood count (CBC) module for the first and second events in 2019. Record review include 2019 and 2020 PT event documents. Findings include: 1. Review of the CASPER Report 0096D CLIA Application and Survey Summary revealed lack of documentation of scores for the first and second events in 2019. 2. A phone call with an American Proficiency Institute (API) service representative on 03/04/21 at 11:18 AM confirmed that the site did not enroll with their hematology (CBC) module until 10/29/19. In addition, review of the available API hematology PT records on 03/04/21 for 2019 and 2020 revealed lack of documentation of enrollment with a PT program for the CBC module. 3. An interview with the lab consultant and primary testing personnel on 03/09/21 at 11:00 AM confirmed that the lab did not enroll for the first two events in 2019 for the CBC module.
D2127	HEMATOLOGY CFR(s): 493.851(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event. This STANDARD is not met as evidenced by: Based on the review of proficiency testing (PT) documents and interview, the laboratory failed to submit one (1) of 4 PT events within the PT program's established timeframe in the calendar year 2020. PT events reviewed include one event in 2019 and three events 2020. Findings include: 1. Review of the CASPER Report 0096D CLIA Application and Survey Summary revealed the lab received a score of 0% for the second event in 2020. 2. Review of the American Proficiency Institute (API) records revealed documentation by the lab director that the lab staff failed to submit the results of the 2nd Hematology Event within the timeframe established by API. The lab received a score of 0%. 3. An interview with the lab consultant and primary testing personnel on March 09, 2021 at approximately 11:30 AM confirmed the findings.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

	This STANDARD is not met as evidenced by: Based on the review of the manufacturer operator's guide, lack of documentation, and interview, the lab failed to perform the monthly maintenance for the Medonic M-series hematology analyzer for twenty-five (25) of 25 months. Dates of record review include January 1, 2019 and up to the date of survey on March 9, 2021. Findings include: 1. Review of the manufacturer operator's guide revealed instructions for performing monthly cleaning procedures utilizing the Boule Cleaning Kit (cleaning procedure and clot prevention) listed under "Section 8: Cleaning, Maintenance & Transport", "8.2 Monthly Cleaning". 2. Review of the available maintenance records for the analyzer revealed lack of documentation of the performance of the monthly maintenance. Dates of record review include January 1, 2019 and up to the date of survey on March 9, 2021 (25 months). The inspector requested to review aforementioned documents on 03/09/21 at approximately 12:00 PM. The primary testing personnel stated that they were not aware that the procedures needed to be done on the instrument and did not perform the procedures. 3. An interview with the lab consultant and primary testing personnel on 03/09/21 at 12:45 PM confirmed the findings.