

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0917412	(X3) Date Survey Completed 06/15/2018
Name of Provider or Supplier Chp-Cvfp Staunton River	Street Address, City, State 527 Pocket Road, Hurt, 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 Staunton River Family Practice on June 15, 2018 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirement. Specific deficiencies cited are as follows:
D2004	<p>ENROLLMENT CFR(s): 493.801(a)(3)</p> <p>For each specialty, subspecialty and analyte or test, participate in one approved proficiency testing program or programs, for one year before designating a different program and must notify CMS before any change in designation;</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing (PT) records and an interview with the laboratory's compliance specialist, the laboratory failed to participate in a proficiency testing program for one year before designating a different proficiency program in calendar year 2016. Record review was from May 2016 to June 2018. Findings include: 1. Review of the laboratory's PT records revealed the laboratory participated in the following: American Proficiency Institute (API) for 2016 Hematology First and Second Events, American Academy of Family Physicians for 2016 Hematology Event C, American Academy of Family Physicians for 2017 Hematology Events A, B, and C; American Academy of Family Physicians for 2018 Hematology Event A. 2. An interview with the compliance specialist at approximately 09:45 AM on 6/15/18 confirmed that the laboratory did not participate in one approved PT program for one year before designating a different program.</p>
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must</p>

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 a review of the laboratory's proficiency testing (PT) records and an interview with the compliance specialist, the laboratory director and testing personnel failed to sign one (1) of seven (7) attestation statements reviewed. Record review was from May 2016 to June 2018. Findings include: 1. Review of the American Proficiency Institute (API) PT records for the 2016 Hematology First and Second Events, American Academy of Family Physicians (AAFP) 2016 Hematology Event C, 2017 Hematology Events A, B, C and 2018 Hematology Event A (a total of seven events) revealed the attestation statement for one event, API 2016 Hematology Second Event, was not signed by the laboratory director and testing personnel. 2. In an interview with the compliance specialist at approximately 09:45 AM on 6/15/18, it was confirmed that one (1) of the seven (7) attestation statements reviewed were not signed by the laboratory director and testing personnel.

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 review of the laboratory's proficiency testing (PT) documentation, and interview with the laboratory's compliance specialist, the laboratory failed to retain documentation of the hematology analyzer's results for one (1) of seven (7) events reviewed. Record review was from May 2016 to June 2018. Findings include: 1. Review of the American Proficiency Institute (API) records for the 2016 Hematology First and Second Events, American Academy of Family Physicians (AAFP) 2016 Hematology Event C, AAFP 2017 Hematology Events A, B, C and AAFP 2018 Hematology Event A (a total of seven events), revealed no Medonic instrument printouts or submitted result documentation for the API 2016 Hematology Second Event. 2. In an interview with the compliance specialist at approximately 09:45 AM on 6/15/18, it was confirmed that the laboratory failed to retain copies of the Medonic analyzers result printouts and submitted results documentation for the API 2016 Hematology Second Event.