

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D1076444	(X3) Date Survey Completed 08/19/2019
Name of Provider or Supplier Craig County Health Center	Street Address, City, State 226 Market Street, New Castle, 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 unannounced CLIA off-site proficiency testing desk review of Craig County Health Center was conducted on August 19, 2019 by a Medical Facilities Inspector of the Virginia Department of Health's Office of Licensure and Certification. The laboratory was inspected under 42 CFR Part 493 CLIA regulations. Specific deficiencies cited are as followed:
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on the proficiency testing (PT) off-site desk review of the laboratory's PT records and a phone interview with testing personnel (TP), the laboratory failed to enroll in a Center for Medicare and Medicaid Services (CMS) approved PT program for the first and second events in 2019. Findings include: 1. Review of the CASPER 164- PT Failure to Re-Enroll Report for 2019, and CASPER 155 Individual Laboratory Report revealed no documentation of PT scores for the hematology module for the first and second events in 2019. 2. A phone interview with the TP-1 (see attached TP code sheet) at approximately 10:20 AM confirmed that the laboratory did not have PT scores for the hematology module for the first and second events in 2019.</p>