

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0232508	(X3) Date Survey Completed 01/13/2022
Name of Provider or Supplier Family Physicians Of Marion	Street Address, City, State 1020 Terrace Drive - Suite 200, Marion, 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 Family Physicians of Marion on 01/13/22 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: The laboratory was not in compliance with the following 42 CFR part 493 CLIA Regulations: D2000 - 42 C.F.R. 493-803 Condition: Enrollment and Testing of Samples. **REPEAT DEFICIENCY**
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 review of proficiency testing (PT) records, lack of documentation, and interview with the testing personnel, the lab director failed to review and sign three (3) of 3 attestation statements in 2020. Refer to D2009 **REPEAT DEFICIENCY**</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 attest to the routine integration of the samples into the patient workload using the</p>

laboratory's routine methods.

This STANDARD is not met as evidenced by:

****REPEAT DEFICIENCY**** Based on the review of proficiency testing (PT) records, lack of documentation, and interview with the testing personnel, the lab director failed to review and sign three (3) of 3 attestation statements in 2020. Findings include: 1. Review of the Medical Laboratory Evaluation (MLE) PT results revealed the lack of documentation of the attestation statements by the lab director for review and signature of all three events in 2020 for the Hematology module. 2. An exit interview with the testing personnel on 01/13/22 at approximately 12 PM confirmed the findings.