

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 49D0232508	<b>(X3) Date Survey Completed</b> 09/24/2019
<b>Name of Provider or Supplier</b> Family Physicians Of Marion	<b>Street Address, City, State</b> 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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An announced CLIA Recertification survey was conducted at the Family Physicians of Marion on September 24, 2019 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:
<b>D1001</b>	<p><b>CERTIFICATE OF WAIVER TESTS</b> CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on the review of lab temperature logs, tour of the lab testing area, manufacturer requirements, and an interview with the primary testing personnel, the lab failed to follow manufacturer's instructions for the storage of the Alere Triage BNP Quality Control (QC) materials Levels 1 and 2 for twenty (20) of 20 months reviewed. Dates of record review include January 1, 2018 and up to August 30, 2019. Findings include: 1. Review of the temperature logs for the laboratory revealed documentation of freezer temperatures January 1, 2018 and up to August 30, 2019 (20 months). The temperature range listed at the bottom of the pages were less than or equal to -30 degrees Celsius. 2. Tour of the lab testing area and an interview with the primary testing personnel at approximately 11:30 AM revealed that the lab stores the Alere Triage BNP QC materials (Levels 1 and 2) in the freezer. 3. Review of the manufacturer requirements for storage of the above-specified QC materials revealed the temperature range of - 20 degrees Celsius or colder. The recorded freezer temperatures was warmer than -20 Celsius for the 20 months reviewed. 4. An interview with the primary testing personnel at approximately 12:15 PM confirmed the findings.</p>

**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 an interview the primary testing personnel, the laboratory director failed to sign one (1) of five (5) attestation statements reviewed. PT record review included 2018 and 2019 (First and second) testing events. Findings include: 1. Review of the Medical Laboratory Evaluation (MLE) PT records for all three events in 2018 and the first and second events in 2019 revealed that the laboratory director did not sign the 2018 MLE 2nd event (M2) attestation statement. 2. An interview with the primary testing personnel at approximately 12:15 PM confirmed the above-listed findings.