

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D1026829	(X3) Date Survey Completed 02/07/2019
Name of Provider or Supplier First Care Family Medicine - Mena	Street Address, City, State 1706 Highway 71 North, Mena, AR	
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
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Through a review of the Eightcheck-3WP X-TRA package insert, quality control documentation for September and November of 2018 and January 2019, and an interview with the laboratory director, it was determined the laboratory failed to follow manufacturer's instructions for the use of the Eightcheck-3WP X-TRA quality control material. Survey findings include: A. Through a review of the Eightcheck-3WP X-TRA package insert it was determined that in the section labeled "Performance characteristics and limitations" the package insert stated, "The assay values are obtained using instrument manufacturer's recommended reagents. The values obtained on Eightcheck-3WP X-TRA should be within the expected ranges." B. Through a review of data entered into the pocH-100i hematology instrument for the new lot of controls started on 11/14/2018 it was determined the laboratory set their quality control target values for RBC (red blood cell count) on the High Abnormal control outside the manufacturer's expected ranges. The RBC expected range for RBC listed on the package insert was 4.98 to 5.50. The target value programmed into the instrument was 4.97. C. In an interview, at 11:02 on 2/7/2019, the laboratory director confirmed the laboratory had set the RBC target mean outside of the manufacturer's expected range.</p>