Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D1007998	(X3) Date Survey Completed 12/19/2019
Name of Provider or Supplier Harmony Healthcare Pllc	**Street Address, City, State** 1361 S Alma School Rd, Mesa, AZ	

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
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of performance verification activities for the AU480 chemistry conducted in December 2018 and interview with the facility personnel, the laboratory failed to verify the accuracy of the method prior to patient testing for the following analytes:Apo A1, Apo B, CK, Homocysteine, hsCRP and Lipase. Findings include: 1. There was no documented comparative analysis between samples analyzed by the laboratory compared with samples that were analyzed by another CLIA certified laboratory. Comparative analysis studies were performed for other analytes during the performance verification as a means to verify accuracy. 2. The facility personnel stated that the laboratory utilized to test samples for the comparative analysis did not perform testing for the the analytes indicated above. 3. Other performance verification specifications for the analytes indicated above were signed off for acceptance by the laboratory director on 01/14/2019.