Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	46D0524018	08/09/2019
Name of Provider or Supplier	**Street Address, City, State**	
Foothill Family Clinic-North	2295 Foothill Drive, Salt Lake City, UT	

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 ACT Diff II verification records review, lack of documentation, and interview with the technical consultant the laboratory failed to verify the reportable range for the ACT Diff II instrument implemented in April 2018. The laboratory performed approximately 3 to 8 CBC tests per day. Findings include: 1. ACT Diff II verification records review included documentation the laboratory received the ACT Diff II instrument in April 2018. The laboratory lacked documentation they verified the instrument reportable ranges for White Blood Cell, Red Blood Cell, and Platelet counts, Hemoglobin concentration, and Mean Corpuscular Volume measurements prior to testing patient specimens. 2. In an interview conducted on 08/09/2019 at approximately 3:30 P.M. the laboratory technical consultant confirmed the laboratory did not perform reportable range verification prior to testing and reporting patient samples.