

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D1004961	(X3) Date Survey Completed 03/27/2019
Name of Provider or Supplier Intermountain Alta View Clinic	Street Address, City, State 9450 S 1300 E, Sandy, 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	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on verification documentation review, lack of documentation and interview with the technical consultant, the laboratory failed to verify the reportable range for complete blood count tests performed on the XS 1000i instrument transferred to the laboratory from Sandy Clinic. The laboratory performed approximately 10 complete blood counts per day. Findings include: 1. Verification documentation failed to include an approved reportable range verification study to ensure the instrument could accurately report values at the manufacturer's or laboratory's lower and upper levels for white blood cell counts, red blood cell counts, hemoglobin, hematocrit, mean corpuscular volume, and platelets. 2. In an interview conducted on 03/27/2019 the technical consultant confirmed a reportable range study was not performed for the instrument transferred to the Alta View Clinic on 2/10/2018.</p>