

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0117604	(X3) Date Survey Completed 06/20/2018
Name of Provider or Supplier Minniti Center For	Street Address, City, State 174 Democrat Road, Mickleton, NJ	
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 surveyor review of Performance Specifications (PS) records and interview with the Testing Personnel (TP), the laboratory failed to verify accuracy for Hematology tests performed on the Beckman Coulter Act 2 analyzer before reporting patient test results from December 2017 to the date of survey. The TP confirmed on 6/20/18 at 10:00 am that accuracy was not done.</p>