

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2222634	(X3) Date Survey Completed 10/05/2021
Name of Provider or Supplier Psh Cmg Andrews Patel Hematology/Oncology	Street Address, City, State 355 N 21st Street, Suite 301, Camp Hill, PA	
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 review of the Beckman Coulter DxH50 analyzer validation records and interview with Technical consultants (TC) #1, the laboratory failed to establish criteria for acceptable performance specifications for Complete Blood Count (CBC) from September 17, 2021 to the date of survey. Findings Include: 1. On the day of survey 10/05/2021, review of the Beckman Coulter DxH50 analyzer validation records revealed, the laboratory did not demonstrate performance specification criteria for accuracy and precision on the validation done on 9/17/2021. 2. From 9/30/2021 to 10/05/2021, the laboratory analyzed 6 patients specimens on the Beckman Coulter DxH50 for CBC. 3. TC #1 confirmed the finding above on 10/05/2021 around 11:10 a. m.</p>