

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0107146	(X3) Date Survey Completed 09/25/2019
Name of Provider or Supplier Union Internal Medicine Group Pa	Street Address, City, State 2027 Morris Avenue, Union, 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 the Performance Specification (PS) records and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to ensure that PS procedures were performed on the Cell Dyn Emerald analyzer for Hematology from 3/23/18 to the date of survey. The finding includes: 1. The laboratory did not perform Precision. 2. The TP #1 listed on the CMS form 209 confirmed on 9/25/19 at 11:15 am that all PS records were not performed.</p>