

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0999301	(X3) Date Survey Completed 06/07/2022
Name of Provider or Supplier Upmc Hcc Mt Pleasant-Upmc Magee	Street Address, City, State 508 South Church Street, Suite 202, Mount Pleasant, 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 DXH 520 analyzer validation records and interview with the Laboratory Manager (LM), the laboratory failed to establish criteria for acceptable performance specifications for Complete Blood Count (CBC) performed on 1 of 2 DXH 520 analyzers from October 1, 2020 to June 7, 2022 . Findings Include: 1. On the day of survey, 06/07/2022 at 09:51 am, review of the 1 of 2 Beckman Coulter DXH 520 analyzers validation records revealed, the validation performed on 10/01/2020 did not include criteria for acceptable precision and accuracy. 2. The laboratory performs annually 45,720 patient testing. 3. The LM confirmed the finding above on 06/07/2020 at 11:00 am.</p>