

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0154551	(X3) Date Survey Completed 07/31/2018
Name of Provider or Supplier Optum Medical Care Pc	Street Address, City, State 100 North Centre Avenue, Suite 300, Rockville Centre, NY	
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
D5437	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.</p> <p>This STANDARD is not met as evidenced by: Based on a surveyor's review of hematology calibration records and interview with the laboratory director/testing person and the laboratory administrator, calibration of the hematology analyzer was not performed at the frequencies required by the laboratory's calibration protocol and by the manufacturer of the analyzer. FINDINGS: 1. The laboratory is using the Horiba ABX Micros 60 analyzer. The laboratory's calibration policy and the manufacturer of the hematology analyzer require analyzer calibration every six months. 2. On July 31, 2018 at approximately 11:00 AM the laboratory director/testing person and the laboratory administrator confirmed that the documentation of the Horiba ABX Micros 60 analyzer calibration available for review was for calibration performed on 6/30/17 and on 6/22/18. The hematology analyzer was therefore out of calibration from 12/31/17 through 6/21/18. 3. Approximately 500 patient specimens were tested and reported for hematology during the above time period when analyzer was out of calibration.</p>