

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0160263	(X3) Date Survey Completed 03/12/2018
Name of Provider or Supplier Optum Medical Care Pc	Street Address, City, State 1021 Old Country Road, Plainview, 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
D2010	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2)</p> <p>The laboratory must test samples the same number of times that it routinely tests patient samples.</p> <p>This STANDARD is not met as evidenced by: Based on a surveyor's review of proficiency testing records and an interview and confirmed with the testing person, the laboratory routinely tests patient Hematology samples once, but tested proficiency testing samples in duplicate for all three events in 2016, 2017 and the first event in 2018.</p>
D5221	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on a surveyor's review of College of American Pathologists (CAP) Proficiency Testing (PT) reports and interview with the testing personnel and the laboratory administrator, the laboratory failed to evaluate, perform and document remedial action for the PT scores less than 100%. Findings: 2016 second event: Hematocrit = 80% Hemoglobin = 80% Platelets = 80% 2016 third event: White Blood Cells = 80%</p>
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</p>

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.

This STANDARD is not met as evidenced by:

Based on a surveyor's review of hematology calibration records and interview with the laboratory 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 ABX Micros 60 analyzer. The laboratory's calibration policy and the manufacturer of the hematology analyzer require analyzer calibration every six months. 2. On March 12, 2018 at approximately 11:00 AM the laboratory testing person confirmed that the documentation of the ABX Micros 60 analyzer calibration available for review was for calibration performed on 12/15/16, 3/16/17 and 2/14/18. The hematology analyzer was therefore out of calibration from 9/17/17 through 2/13/18. 3. Approximately 300 patient specimens were tested and reported for hematology during the above time period when analyzer was out of calibration.