

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0675313	(X3) Date Survey Completed 09/11/2019
Name of Provider or Supplier American Oncology Partners, P A	Street Address, City, State 18223 E Ten Mile Road Suite 100, Roseville, MI	
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
D5781	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the office liaison and Testing Personnel #1 (TP1), the laboratory failed to document the corrective action taken for humidity readings outside the expected range for 4 (January, February, March, and April 2019) of 24 months reviewed from September 2017 to September 2019 for the proper operation of the hematology Beckman Coulter AcT diff 2 analyzer and the chemistry Dimension EXL 200 analyzer. Findings include: 1. Record review of the "Room Temperature & Humidity Log" showed the acceptable range for the humidity is 20-80%. 2. Record review of the "Room Temperature & Humidity Log" revealed for 4 of 24 months the humidity readings were below the expected range of 20-80% as follows: a. January - 9, 22-24, and 28-31 b. February - 12-15, 18-19, 21-22, and 27 c. March - 4-5, 8, 11, 13-15, 18-19, 22, 26-27, and 29 d. April - 10-12, 16, and 29 3. During the interview on September 11, 2019 at 1:30 p.m., the office liaison and TP1 confirmed no corrective action was documented for the readings outside the stated range.</p>