Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D1084432	11/20/2020
Name of Provider or Supplier	**Street Address, City, State**	
Affinity Physician	3686 Grandview Parkway, Suite 820, Birmingham, AL	

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
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on a review of the 2018 - 2020 API (American Proficiency Institute) Proficiency Testing records and an interview with the Technical Consultant, the laboratory failed to document corrective action for two of eight surveys with results less than 100 % (percent). The findings include: 1. A review of the API Proficiency Testing survey results revealed no documentation of investigation or corrective action for two surveys with results less than 100% as follows: A) 2018 Event #2 Hematology: Granulocytes and Monocytes each with scores of 80%, resulting in a score of 87% for the WBC (White Blood Cell) Differential, and B) 2020 Event #1 Urine Sediment with a score of 50%. 2. In an interview on 11/24/2020 at 11:00 AM, the Technical Consultant reviewed and confirmed the above noted findings. .
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) 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. This STANDARD is not met as evidenced by: Based on reviews of the Beckman Coulter AcT diff 2 Hematology analyzer Operator's Manual, calibration and quality control (QC) records, and interviews with the Technical Consultant and the Testing Personnel, the laboratory failed to follow the policy in the performance frequency of calibrations in 2018, and further failed to follow the manufacturer's instructions to verify calibrations by running quality controls (QC), for one out of four calibrations of the Hematology analyzer performed in the 2018 - 2020 survey review period. The findings include: 1. A review of the Hematology records revealed the following: A) 01/11/2018: Documentation of a calibration (reviewed during the previous survey) B) 12/13/2018: Documentation of a second 2018 calibration (performed eleven months after the previous calibration) C) 06/21/2019 at 1:26 PM: Documentation of a calibration, however the records did not include results of the QC used to verify the calibration. 2. A review of the QC records revealed controls were run in the early morning at approximately 9:00 AM on 6/21 /2019; however, there was no documentation QC was performed after the calibration. 3. A review of the Coulter AcT diff 2 Analyzer Operator's Guide, under the CALIBRATION section on page 5-18 revealed, "...17. Verify calibration by running 4C PLUS Cell Control. ..." 4. During an interview on 11/24/2020 at 11:02 AM, the surveyor asked if the laboratory had performed an earlier calibration in mid-2019. The Technical Consultant stated the laboratory had missed performing the calibration when it was due because the calibrator was not received in a standing order. The surveyor then asked how often a calibration should be performed; the Technical Consultant answered, "Every six months". 5. During a second interview on 11/24 /2020 at 1:40 PM, the surveyor reviewed the 6/21/2020 calibration with the Testing Personnel, who confirmed she had missed performing QC after the calibration, as was required. Thus the above noted findings were confirmed. SURVEYOR ID #32558 Licensure and Certification Surveyor