Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D1089574	05/02/2018
Name of Provider or Supplier	**Street Address, City, State**	
Affinity Physicians Services	5890 Valley Road Suite 200, 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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on a review of the MLE (Medical Laboratory Evaluation) proficiency testing (PT) records and an interview with Testing Personnel #4, the laboratory failed to retain the attestation statements for five out of six 2016-2018 survey events. The findings include: 1. A review of MLE proficiency testing records revealed the laboratory failed to retain the attestation statements for five Hematology surveys: 2016-M2 and M3, 2017-M1 and M2, and 2018-M1. 2. During an interview on 5/2 /2018 at 1:45 PM, Testing Personnel #4 stated she had mailed the attestation statements with the results to MLE, but had failed to make a copy of the attestation statements for their records. Thus the above noted findings were confirmed. .
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling,

	storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on a review of the policies and procedures and an interview with Testing Personnel #4, the surveyor determined the laboratory failed to ensure the Policy and Procedure Manual included a protocol to follow when patients' CBC (Complete Blood Count) results yielded imminent life threatening results or panic values. The findings include: 1. A review of the laboratory policy and procedure manual revealed there was also no protocol to follow when testing personnel obtained imminent life threatening results or panic values. 2. During an interview on 5/2/2018 at 2:00 PM, Testing Personnel #4 was asked if the laboratory had a written protocol to follow when patient samples yielded imminent life threatening results. After a review of the records and a discussion with the Technical Consultant, Testing Personnel #4 stated she was unable to find a procedure. Thus, the above noted findings were confirmed. .
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on a review of the Abbott Cell Dyn Emerald Hematology analyzer Operator's Manual and an interview with Testing Personnel #4, the laboratory failed to ensure the Laboratory Director signed, dated and approved the manual for use by the testing personnel. The findings include: 1. A review of the Abbott Cell Dyn Emerald Hematology analyzer Operator's Manual revealed no signature and date of the current Laboratory Director to indicate her review and approval of the manual for use by the testing personnel. 2. During a review of the manual with Testing Personnel #4 on 5/2 /2018 at 2:00 PM, this observation was confirmed. .
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 Abbott Cell Dyn Emerald Hematology analyzer Operator's Manual, calibration records, and an interview with Testing Personnel (TP) #4, the surveyor determined the laboratory failed to follow the manufacturer's instructions in the performance frequency of calibrations in 2016 - 2017. The findings include: 1. A review of the Abbott Cell Dyn Emerald Hematology analyzer Operator's Manual on page 6-3 revealed the following instructions, "When to Calibrate...At least every six months...". 2. A review of the Hematology records revealed the following: A) 12/13/2015: Documentation of a complete calibration reviewed during the previous survey B) 06/30/2017: Documentation of a calibration performed one and a half years after the previous calibration C) 09/22/2017: Documentation of a calibration performed three months later during a service call D) 05/01/2018: Documentation of a calibration performed seven and a half months after the previous calibration 3. During an interview and review of the records on 5/2/2018 at 1:45 PM, TP #4 was asked if the laboratory had documentation of Hematology calibrations performed in 2016. TP #1 explained there had been a problem with the automatic ordering of the calibrators in 2016, and the Hematology calibrations had been missed. When asked if there had been a calibration after the 9/22/2017 service call in late 2017 or early 2018, TP #4 stated there had been no other calibrations until 5/1/2018. When asked how often the Hematology analyzer should be calibrated, TP #4 stated, "Every six months". Thus, the above noted findings were confirmed. SURVEYOR: Laura T. Williams, BS, MT (ASCP) Licensure and Certification Surveyor