Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0993254	07/12/2018
Name of Provider or Supplier	**Street Address, City, State**	
Auerbach Hematology Oncology Assoc Pc	5233 King Avenue, #308, Baltimore, MD	

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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of proficiency test records, the laboratory (lab) director did not sign attestation records for one of six proficiency test events reviewed. Findings: 1. For each proficiency test event the laboratory director is required to sign an attestation declaring that the unknown test samples will be tested in the same manner as patient samples; and 2. It was observed, during record review that the lab was missing the attestation statement (signed by the lab director) for the first hematology event in 2017.
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 review of hematology proficiency test records, the lab records did not include the identification of the testing person performing the blood cell morphology challenge. Findings: 1. The testing person was not identified in the blood cell morphology/identification testing records for the first event of 2018; 2. The testing person was not identified in the blood cell morphology/identification testing records for the third and second event of 2017; and 3. The testing person was not identified in the blood cell morphology/identification testing records for the third and second event of 2016.
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on observation and interview, the laboratory (lab) did not follow written procedures to label patient slides to ensure positive identification of the patient slides. Findings: 1. The laboratory performs a Wright's stain on the patient blood that is prepared on the glass slide. The patient slide is then observed under the microscope and the observations are resulted onto a patient log and transcribed into the patient chart; 2. The lab procedure posted on the automatic slide stainer instructs the lab to label slides with the patient name and date; 3. All ten of the most current slides sitting on the counter alongside the microscope were observed to be labeled with the patient name only; and 4. At 10:00 am on the day of survey this observation was confirmed during interview with lab staff.
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 interview with lab staff at 1:00 pm on the day of survey, the lab did not have a written procedure to notify testing staff when results of hematology quality control reagents (tested on the automated analyzer) failed to meet the labs criteria for acceptability for either the closed or capillary mode of testing to ensure staff do not report test results using failed mode.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation and interview with laboratory (lab) staff, the lab did not ensure reagents were not used past expiration. Findings: 1. At 10:30 am the surveyor observed that there were 58 individual tubes of hematology quality control reagents next to the hematology analyzer, five of the tubes were examined and were expired; 2. During interview of lab staff at 10:30 am, staff stated that the control reagents next to the hematology analyzer were expired and the lab scanned the labels on the expired tubes to look up the files; 3. The lab did not label the rack of expired reagents with a warning to not use in patient testing; 4. The lot number of the low, normal and high levels of the automated hematology quality control reagents are documented on the quality control assessment record and from July18, 2016 to September 30, 2016 the record was not completed and the lot numbers of the controls were not recorded.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on observation, the laboratory (lab) did not maintain the preventive maintenance program. Findings: 1. The lab microscope is located next to the automatic slide stainer; 2. On the microscope is a sticker. The sticker was placed there by the company that performed annual maintenance on the microscope; 3. The last date of service printed on the sticker was October 22, 2015 and the next service due date was October 2016; and 4. The due date had passed and there was no other service sticker fastened to the microscope showing annual maintenance was performed.
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 record review and interview, the hematology laboratory did not perform and maintain calibration records for the hematology analyzer. Findings: 1. The laboratory written procedure instructs the lab to perform required biannual calibrations on the hematology analyzer; 2. The lab did not have calibration records for the first half of 2018; 2. In 2017 the only calibration record was dated October 24, 2017 and no earlier record was present in the labs 2017 quality assurance and controls record binder; 3. The calibration performed prior to October 24, 2017 was February 29, 2016, and there were no calibration records for the second half of 2016; and 4. Lab staff was interviewed at 12:30 pm on the day of survey and stated that the calibration records were possibly misplaced.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review, the laboratory (lab) did not record the results of the Wright's stain quality control on the patient worksheet where indicated. Findings: 1. The lab performs wrights staining on patient peripheral blood and bone marrow smears prepared on glass slides for microscopic examination of cell morphology; 2. The lab maintains a log to record the test date, patient identification, patient result and quality control results for the Wright's stain; 3. On the log is a column identified as quality control to document that the staining characteristics observed on the patient slides are acceptable; and 4. The lab did not record quality control observations from January 2018 to the day of survey.
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. This STANDARD is not met as evidenced by: A. Based on record review and interview with lab staff at 2:30 pm on the day of survey, the lab did not ensure hematology corrective action records were complete. Findings: 1. The lab performs quality control testing in both the closed and capillary

	modes (channels)of the hematology analyzer; 2. The closed channel is used to test venous blood collected into a vacutainer tube, and the capillary channel is used to test blood collected by fingerstick. The lab must test quality control reagents (high, normal and low levels) in both modes in order to demonstrate accuracy, and the quality control checks are reviewed for acceptability prior to testing patient samples; 3. The quality control summary report for the results of the high, normal and low levels of control reagent do not identify the mode of testing and the quality control corrective action logs do not contain enough detail to show all the actions taken by the lab (retesting of controls and troubleshooting); 4. The written quality control procedure instructs the lab to "check that results are within a acceptable range" (start up controls procedure); 5. On August 9, 2016 the normal and high level of the automated hematology control was tested 6 times for each level, the quality control assessment was not completed and no decision was reported for the acceptability of the controls; 6. On August 10, 2016, for automated hematology, the normal control level was tested 11 times, the low control level was tested 6 times and the high control level was tested 7 times. the quality control assessment was not completed and no decision was reported for the acceptability of the controls; 7. On May 1, 2018 the high level of the hematology control was tested twice according to the control summary report. The second result did not meet the labs criteria for acceptability for the red blood cell test. The "Quality Control Corrective Action Log" did not have an entry for this date and there was no record that the control results were assessed for acceptability on the log that the lab uses to document "Within Limits (Y/N); 8. The written quality control procedure instructs the lab to "check that results are within a acceptable range" (start up controls procedure). Staff stated that the closed mode is checked with quality control reagents and then the capillary mode is checked, this statement by staff is the basis for determining the mode used for each control described here. On May 17, 2018 the normal level of control was checked three times, the first check was the closed mode (interview with staff) and the second and third check were performed using the capillary mode (interview with staff), but the red cell count did not meet the labs criteria for acceptability for the capillary mode red blood cell test. The high control level for the red blood cell count was out of range for the closed mode on this day and was not repeated (interview with staff). The assessment made for the capillary control was - not within limits, and the assessment for the closed mode was - yes within limits. There was no quality control corrective action documented on the "Quality Control Corrective Action Log" and there are no comments describing the modes the lab allowed testing for. There was no description explaining why the closed mode was acceptable but the capillary mode was unacceptable even though both red blood cell tests did not meet the labs criteria for acceptability; and 9. On January 3, 2018 the "Daily Record of Boule Con-Diff Tri-Level" worksheet states that the first high level control result is not within limits, but it does not instruct staff to not use the closed test mode. B. Based on record review, the laboratory (lab) did not take corrective action when the temperature of the labs refrigerator failed to meet the labs criteria for acceptability. Findings: 1. The lab maintains a refrigerator to store patient specimens and hematology quality control reagents; 2. from November 1, 2016 thru December 30, 2016 all the daily temperature readings were 9 degrees Centigrade (the acceptable range is 2 to 8 degrees Centigrade); and 3. There was no corrective action taken and documented to ensure that the refrigerator was at proper temperature.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time

	of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on record review, the testing person was not identified on two hematology test records recorded on February 23, 2018. Findings: 1. The laboratory performs microscopic examinations on peripheral blood and bone marrow samples collected from patients. The blood or bone marrow is the prepared on a glass slide and stained using Wright's stain. The slides are then examined microscopically and results are reported; and 2. On February 23, 2018 two patients were tested and observed for cellular morphology, but the test log used to document the examination did not identify the testing person.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory director did not ensure that the hematology quality control program was maintained to assure accuracy of automated hematology patient test results. Findings: 1. The monthly quality control summary report is a monthly report of the results of the high, normal and low quality control reagents tested on the automated hematology analyzer; 2. At the time of the survey, the lab could not locate the quality control report that includes quality control results from August 3, 2017 to August 22, 2017; 3. At the time of the survey, the lab could not locate the hematology quality control troubleshooting log for 2017. This log is a record of the actions the lab takes when quality control failures occur; 4. The lab also maintains a corrective action log that is used to document corrective actions when quality control failures, the lab was not able to locate the corrective action log from February 2017 thru December 2017, inclusive; and 5. The findings were confirmed during interview with lab staff at 1:00 pm on the day of survey.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: A. Based on record review the laboratory (lab) director did not date his competency assessments of all eight lab staff in both 2017 and 2016. Findings: 1. Competency

	assessments are performed annually to ensure testing personnel and supervisory personnel perform their duties in a a reliable manner; and 2. In 2017 and 2016 the lab director did not complete the assessment records for his staff because he did not date the records as indicated on the forms. B. Based on record review, the laboratory (lab) director did not assess the technical consultant listed on the CMS form-209 for her supervisory duties, she was only assessed in 2017 for the same duties as the testing personnel. The additional duties typically assigned to a technical supervisor were not evaluated. C. Based on record review, the laboratory (lab) director did not ensure that the competency assessment of the technical consultant was performed in a reliable manner. Findings: 1. The technical consultant listed on the CMS form 209 had competency assessments performed August 19, 2016 and August 11, 2017, and for each assessment performed, the technical consultant signed her own assessment as technical consultant; and 2. Competency assessments are performed by someone who supervises the person being assessed.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on record review and interview with the laboratory (lab) director, the lab was unable to identify a patient documented in the Wrights stain log for a peripheral blood smear test. Findings: 1. The lab maintains a written record or log of patients who have peripheral blood or bone marrow samples prepared, stained and examined. The results of the test examination are reported on the log and transcribed to the patient chart; 2. Patient A was identified on the log, by last name only, the stain was performed on February 23, 2018; 3. The surveyor was not able to locate the slide in the slide storage cabinet; and 4. During interview with the lab director at 2:00 pm on the day of survey, the lab director was unable to identify the patient and retrieve the test results from the patients chart.