Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0950710	01/16/2018
Name of Provider or Supplier	**Street Address, City, State**	
Bel Air Oncology Center	12 Medstar Blvd Suite 180, Bel Air, 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
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: I. Based on review of the procedure manual and interview with technical consultant (TC), the laboratory did not provide the testing personnel with a written procedure for e-mailing the quality control (QC) results to the technical consultant for monthly review and maintaining the electronic review of the QC as part of the laboratory's record system. Findings: 1. According to the testing person the hematology QC results are are printed sent to the TC for review on a monthly basis. The TC responds via e-mail acknowledging receipt and identifying any problems that may need to be corrected by the laboratory. 2. Review of the procedure manual showed that there

	were no written policies and procedures for e-mailing the monthly QC results to the TC for review and documenting the findings of the review. 3. During the exit interview on 01/16/2018 at 1:00 PM the TC confirmed that the procedure manuals did not have written policies and procedures for e-mailing monthly QC results and documenting the findings of the review. II. Based on review of the procedure manual and interview with the testing person and TC, the laboratory did not have written policies and procedures for verifying patient test results, shredding instrument printouts and saving proficiency testing (PT) printouts. Findings: 1. According to the testing person the hematology analyzer is interfaced with the laboratory information system (LIS). Once the hematology patient test results are verified in the LIS the instrument printout with the patients test results are shredded. The instrument printouts for PT are saved with the required PT documentation. 2. Review of the procedure manual showed that there were no written policies and procedures for verifying patient test results, shredding instrument printouts and saving PT printouts. 3. During the exit interview on 01/16/2018 at 1:00 PM the TC confirmed that the procedure manuals did not have written policies and procedures for verifying patient test results, shredding instrument printouts and saving PT printouts.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: I. Based on review of patient final reports and interview with the supervisor and technical consultant, the laboratory did not ensure that the final test report listed the address of the laboratory performing the tests. Findings: 1. When the laboratory moved to the new location in April 2016 they interfaced the hematology analyzer with a Laboratory Information System (LIS) called ARIA. The laboratory is part of a larger system that includes multiple satellite offices. Each satellite office has their own identifier in the ARIA LIS. 2. A final report was printed to verify that the new address was on the final patient test report. The printed report listed the new address of the facility in the upper right hand corner. The final report also listed the old address along with the ARIA LIS identifier. The patient final report listed the old and new address on the final report. 3. During the exit interview on 01/16/2018 at 1:00 PM the laboratory supervisor and technical consultant confirmed that the patients final report listed the old and new address of the laboratory performing the tests. II. Based on interview with the laboratory supervisor, laboratory director and technical consultant, the laboratory did not ensure that the final report listed the address at which the peripheral blood smears were reviewed. Findings: 1. The laboratory supervisor stated that sometimes peripheral blood smear slides are prepared and labeled for some of the doctors in the practice. The slides are taken to the main hospital where they are stained and read by the doctor. The findings of the review of the stained slide are identified in the notes written by the doctor. 2. When interviewed the laboratory director stated that the identification of the site at which the peripheral blood smears

	are read is not part of the final report. 3. During the exit interview on 01/16/2018 at 1: 00 PM the laboratory director and technical consultant confirmed that the patients final report, which includes the doctors observations and notes, did not identify the location at which the interpretation of the peripheral blood smear slides were performed. III. Based on review of the procedure manual and interview with the technical consultant, the laboratory did not ensure that the critical value report given to the doctors listed the name and address at which the testing was performed. Findings: 1. Review of the critical value worksheet found in the procedure manual showed that the report listed the name and address of the parent hospital and not the name and address of the actual testing facility. 2. During the exit interview on 01/16 /2018 at 1:00 PM the technical consultant confirmed that the critical value report did not include the name and address of the actual testing facility.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: I. Based on review of the quality assessment (QA) documents and interview with the technical consultant, the laboratory director did not ensure that the QA documentation was reviewed at the end of each month to ensure the quality of laboratory services. Findings: 1. The QA worksheets require the laboratory director to review the findings that have been assembled in a report at the end of each month. 2. Review of the monthly QA reports from September 2016 through December 2017 show that the laboratory director did not sign and date the documented findings to ensure that the laboratory staff were completing the required tasks each month. 3. During the exit conference on 01/16/2018 at 1:00 PM the technical consultant confirmed that the QA worksheets were not being review by the laboratory director to ensure the quality of laboratory services. II. Based on review of the room temperature and humidity worksheets and interview with the technical consultant, the laboratory director did not ensure that the laboratory staff were monitoring the room temperature and humidity each month of testing to ensure the quality of laboratory services. Findings: 1. The room temperature and humidity worksheets for 2017 were reviewed. The records showed that the room temperature and humidity had not been recorded from March 16, 2017 through June 5, 2017. The laboratory did not monitor the room temperature and humidity for 56 days in the room where the hematology analyzer was being used to test patient samples. 2. The technical consultant stated that the room temperature and humidity monitoring device had been sent to be recalibrated and a second device was not installed to monitor the room temperature and humidity while the first device was being recalibrated. 3. During the exit conference on 01/16/2018 at 1:00 PM the technical consultant confirmed that the laboratory did not monitor the room temperature and humidity for 56 days in the room where the hematology analyzer was being used to test patient samples.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)

	The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of the evaluation documentation and interview with the technical consultant (TC), the TC did not ensure that all testing personnel received an initial and semiannual competency review. Findings: 1. The laboratory currently has eight testing persons listed on the "Laboratory Personnel Report (CLIA) (CMS-209)". 2. The testing personnel evaluation records for 2016 and 2017 were reviewed. Two of the eight files for the testing persons showed only an annual evaluation and did not include documentation of the initial and semiannual evaluations. 3. During the survey on 01/16/2018 at 1:00 PM the TC confirmed that there were no records in the file documenting the initial and semiannual evaluation of two of the eight testing persons listed on the CMS-209.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on review of the evaluation documentation and interview with the technical consultant (TC), the TC did not ensure that all testing personnel received an annual competency review. Findings: 1. The laboratory currently has eight testing persons listed on the "Laboratory Personnel Report (CLIA) (CMS-209)". 2. The testing personnel evaluation records for 2016 and 2017 were reviewed. One of the eight testing persons had documentation of the initial and semiannual evaluation and an annual evaluation for 2017 but no annual evaluation for 2016. 3. During the survey on 01/16/2018 at 1:00 PM the TC confirmed that there were no records in the file documenting the annual evaluation for one of the eight testing persons listed on the CMS-209.