Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1010821	09/25/2018
Name of Provider or Supplier	**Street Address, City, State**	
Coastal Bend Oncology	712 Booty Street, Corpus Christi, TX	

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
D0000	A recertification survey was performed on September 25, 2018. The laboratory was found to be out of compliance with the CLIA regulations. The conditions not met were: D5400 - 42 C.F.R. 493.1250 Condition: Analytic systems D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director D6033 - 42 C.F.R. 493.1409 Condition: Laboratories performing moderate complexity testing; technical consultant D6063 - 42 C.F.R. 493.1412 Condition: Laboratories performing moderate complexity testing; testing personnel The facility representatives were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute (API) proficiency

	testing (PT) records, and confirmed in interview of facility personnel, the laboratory failed to test PT samples the same as patient samples. The findings were: 1. Review of laboratory records revealed the laboratory did not have a proficiency testing policy nor a repeat policy. 2. Review of the laboratory's API PT records from 2017 (event 1, 2, and 3) and 2018 (events 1 and 2) revealed that 2018 (event 2) was tested as follows: HSY-06 Tested: 07/24/2018 @ 09:54 Tested: 07/24/2018 @ 09:55 HSY-07 Tested: 07 /24/2018 @ 0957 Tested: 07/24/2018 @ 0959 HSY-08 Tested: 07/24/2018 @ 10:01 Tested: 07/24/2018 @ 10:04 HSY-09 Tested: 07/24/2018 @ 10:08 Tested: 07/24 /2018 @ 10:11 HSY-10 Tested: 07/24/2018 @ 10:14 Tested: 07/24/2018 @ 10:16 3. An interview with the primary testing person at 11:15 hours in the laboratory confirmed the findings. When asked if the laboratory had any policies or procedures, she stated, "No." She revealed she utilized the operator's manual. When asked why each of the PT samples were tested two times each, she stated, "So I could make sure they were accurate."
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 proficiency testing records and confirmed in interview of facility personnel, the laboratory failed to retain proficiency testing records for 2 years for 1 of 5 events reviewed. The findings were: 1. Review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records for 2017 (events 1, 2, and 3) and 2018 (events 1 and 2) revealed the laboratory failed to retain the following records: a. Attestation Statement - 2018 (event 1) b. Instrument Printouts - 2018 (event 1) 2. An interview with the primary testing person on September 25, 2018 at 11: 30 hours in the laboratory confirmed the findings.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute (API) proficiency testing records, and confirmed in interview of facility personnel, the laboratory failed to evaluate proficiency testing results for 1 of 5 events reviewed. The findings were: 1. Review of the laboratory's API proficiency testing records for 2018 (event 1) revealed the laboratory received the following scores: Erythrocyte Count: 100

	Hematocrit: 100 Hemoglobin: 100 Leukocyte Count: 100 Platelet Count: 100 White Blood Cell Diff: 100 2. Further review of the laboratory's API proficiency testing records from 2017 (events 1, 2, and 3), and 2018 (events 1 and 2) revealed the laboratory failed to review and evaluate 2018 (event 1). 3. Review of the API "Proficiency Testing Performance Evaluation" stated, "After reviewing the evaluation reports, complete the information below and retain this form along with the enclosed reports for your records." There was a place for the laboratory director or designee to sign and date the form. The form was not signed or dated. 4. Interview of the primary testing person at 1115 hours in the laboratory confirmed the findings. Upon her review of the evaluation sheet, she agreed it was not reviewed or signed.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on direct observation, and confirmed in interview of facility personnel, the laboratory failed to establish a written policy for specimen labeling. The findings were: 1. Direct observation made in the laboratory on September 25, 2018 at 10:15 hours during the initial tour of the laboratory revealed 10 purple top (EDTA) samples in a Styrofoam rack. 5 of 10 samples were not labeled with any identifying information 5 of 10 samples had first and last name only 2. An interview with the primary testing person on September 25, 2018 at 11:15 hours in the laboratory confirmed the findings. She confirmed the laboratory did not have a specimen labeling policy. When asked how she can identify the tubes of blood, she stated, "I bring the patient chart into the room with me." When asked to print the report associated with the tube of blood the surveyor was pointing to, she stated, "I see what you are saying now." Key: EDTA - ethylenediaminetetraacetic acid
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on direct observations, review of laboratory policy, review of quality assessment records and confirmed in interview of facility personnel, the laboratory failed to establish written policies to identify and correct problems in its preanalytic systems as evidenced by: 1. The laboratory failed to have a quality assurance policy that would identify and correct when specimens are not labeled correctly (refer to D5311).
D5400	ANALYTIC SYSTEMS

	CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on direct observations, review of manufacturer's instructions, review of quality control records, review of patient records, review of environmental records, review of maintenance records, and confirmed in interview of facility personnel, the laboratory failed to monitor overall quality of its analytic systems as evidenced by: 1. The laboratory failed to follow the manufacturer's instructions to ensure flags are resolved prior to their release to the healthcare provider (refer to D5411-A). 2. The laboratory failed to follow the manufacturer's instructions for BD (Becton Dickinson) blood collection tubes to ensure tubes are adequately filled (refer to D5411-B). 3. The laboratory failed to monitor room temperature, room humidity, and and refrigerator conditions as required by the manufacturer (refer to D5413). 4. The laboratory failed to ensure reagents were properly labeled with identification, concentration, storage requirements, and dates (refer to D5415). 5. The laboratory failed to monitor revised quality control expiration dates on Sysmex XP-300 quality control reagents (refer to D5417). 6. The laboratory failed to provide documentation of a verification study for the Sysmex XP-300 hematology analyzer (refer to D5421). 7. The laboratory failed to provide documentation of performing required manufacturer maintenance procedures (refer to D5429). 8. The laboratory failed to have a policy for establishing quality control procedures to detect immediate errors and errors over time (refer to D5441). 9. The laboratory failed to provide documentation of establishing its own target values for new lots of quality controls on the Sysmex XP-300 (refer to D5469).
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: A. Based on review of the manufacturer's instructions for the Sysmex XP-300 hematology analyzer, random review of patient test results from March 2018 to September 2018, and confirmed in interview of facility personnel, the laboratory failed to provide documentation of performing corrective actions as required by the manufacturer to ensure CBC (complete blood count) samples with flags were verified prior to release to the healthcare provider. The findings were: 1. This is a repeat deficiency from the survey dated November 1, 2016. 2. A review of the manufacturer's instructions for the Sysmex XP-300 hematology analyzer (Code No. AU553517, Revised May 2014) under the section titled "Analysis of Histogram" stated, "Analysis of histogram allows use of the flagging system that suggests sample error or instrument error." 3. A review of the manufacturer's instructions for the

	Sysmex XP - 300 hematology analyzer (Code No. AU553517, Revised May 2014) Section 8.3 "Histogram flags" states: "Flag: WL - Incomplete lysing of red blood cells, presence of nucleated red blood cells, increase of large platelets, platelet aggregation or agglutination, precipitation of fibrin, etc. Correction (reference): a. Centrifuge sample and replace the plasma with equal volume of saline or CELLPACK and repeat analysis. b. Check smear, etc." "Flag: F1 - Presence of CML or other immature granulocytes, sample high values for monocytes, eosinophils, and basophils, incomplete lysing of red blood cells, aged sample, etc. Correction (reference): a. Check smear, etc. b. Centrifuge the sample and replace the sample with equal volume of saline or CELLPACK and repeat analysis, warm sample at 37 degrees Celsius and repeat analysis, etc." "Flag: F2 - Presence of CML or other immature granulocytes, sample high values for monocytes, eosinophils, and basophils, incomplete lysing of red blood cells, aged sample, etc. Correction (reference): a. Check smear, etc. b. Centrifuge the sample and replace the sample with equal volume of saline or CELLPACK and repeat analysis, warm sample at 37 degrees Celsius and repeat analysis, etc." "Flag: RU - Effects of cold agglutination, inclusions of white blood cells, etc. Correction (reference): a. Warm sample at 37 degrees Celsius and repeat analysis, etc." b. Check smear, etc. "Flag AG - Presence of nucleated red blood cells, effects of fragmented red blood cells, increase of large platelets, platelet aggregation or agglutination, precipitation of fibrin, etc. Correction (reference): a. Check smear, etc. 4. A random review of patient results from January 2018, February 2018, April 2018, and August 2018 revealed the following patients' whose CBC results had flags: Date Patient Flag 01/30/18 see alias report AG 01/31/18 see alias report AG 02/02/18 see alias report AG 02/19/18 see alias report WL 04/09/18 see alias report AG 08/07 /18 see alias report AG 5. An interview with the primary testing person on September 25, 2018 at 15:00 hours in the laboratory confirmed the findings. B. Based on direct observation, review of manufacturer's instructions, and confirmed in interview of facility personnel, the laboratory failed to follow the manufacturer's instructions to fill tubes completely. The findings were: 1. Direct observation made in the laboratory on September 25, 2018 at 10:15 hours revealed 10 patient samples in a styrofoam rack. Each of the 10 of 10 EDTA specimens was under filled; 2 were half full and 8 were full. 2. Review of the manufacturer's instructions for BD (Becton Dickinson) Evacuated Blood Collection System (04/2018, VDP40161-WEB-08) under "Caution" stated, "8. Overfilling or under filling of tubes will result in an incorrect blood-to-additive ratio and may lead to incorrect analytic results or poor product performance." 3. An interview with the primary testing person on September 25, 2018 at 11:15 hours in the laboratory confirmed the findings. When asked if the routine practice was to fill the tubes about to full she said, "Yes." She went on to confirm that many patients were hard sticks. Key: EDTA - ethylenediaminetetraacetic acid
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by:

	Based on direct observation, review of the manufacturer's instructions for the Sysmex XP-300 hematology analyzer, review of the Sysmex EIGHTCHECK-3WP X-TRA hematology controls, review of the manufacturer's instructions for the BD (Becton Dickinson) Vacutainer blood collection tubes, surveyor observation of controls and supplies currently in the laboratory, review of environmental records, and staff interview, it was revealed the laboratory failed to have documentation of monitoring room temperature, room humidity, and refrigerator temperature. The findings were: 1. This is a repeat deficiency from the survey dated November 1, 2016. 2. A review of the manufacturer's instructions for the Sysmex XP-300 hematology analyzer (Code No. AU553517, May 2014) under the section titled "14.2 Specifications" revealed the manufacturer's defined operating environment for the analyzer was: Ambient temperature: 15C to 30C Relative humidity: 30% - 85% 3. A review of the manufacturer's instructions for the BD blood collection tubes revealed the manufacturer required the tubes to be stored at a temperature range of 4 - 25C. 4. A review of the manufacturer's instructions for the Sysmex EIGHTCHECK-3WP X-TRA hematology controls (350493-2, Rev. 15, 02/2013) under the section titled "Storage and Stability" stated, "Store EIGHTCHECK-3WP X-TRA vials at 2 - 8C. Storage outside this temperature range risks product damage." 5. Surveyor observation on September 25, 2018 at 10:20 hours during the initial tour of the facility revealed the laboratory stored the following EDTA tubes in the triage room: Lot 80327292 Quantity of 244 6. Surveyor observation of controls stored in the refrigerator on September 25, 2018 revealed two tubes each of the current lot (822707, expiration date: 11-21-18). 7. Review of environmental records revealed the last documented room temperature and humidity and refrigeration entry was March 26, 2018. 8. An interview with the primary testing person and the laboratory director on September 25, 2018 at 17:15 hours confirmed the findings. Key EDTA - Ethylenediaminetetraacetic acid
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: A. Based on direct observation, review of manufacturer's instructions, and confirmed in interview of facility personnel, the laboratory failed to monitor revised expiration dates for Sysmex EightCheck-3WP X-TRA hematology controls. The findings were: 1. Direct observation on September 25, 2018 revealed the following Sysmex EightCheck-2WP X-TRA located in the refrigerator: Lot 822707 (expiration date: 11-21-2018). The low, normal, and high control vials were open. The vials did not have an open date or revised expiration date. 2. Review of the manufacturer's instructions for the Sysmex EightCheck-3WP X-TRA controls (Rev. 15, 02/2013) under "Storage and Stability" stated, " ...Unused material from open vials should be discarded after 14 days." 3. An interview with the primary testing person on September 25, 2018 at 11: 10 hours in the laboratory confirmed the findings. She confirmed the vials were currently in use and that she thought they were opened 2 weeks ago, but could be sure of the date. B. Based on direct observation and interview of facility personnel, the laboratory failed to label reagents with the identification, concentration, storage

	conditions, and dates. The findings were: 1. Direct observation on September 25, 2018 at 10:20 hours in upper right storage cabinet in the laboratory revealed a yellow liquid in a specimen urine cup. The container label was blank. 2. An interview of the primary testing person at 11:15 hours in the laboratory confirmed the findings. She revealed it was a cleaner for the Sysmex XP-300. She agreed that it was not labeled with any identifying information.
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 direct observation and confirmed in interview of facility personnel, the laboratory failed to ensure expired items were not retained passed their expiration date. The findings were: 1. Based on direct observation on September 25, 2018 at 10: 30 hours during the initial tour of the laboratory, the following expired items were observed: a. Liquid QC (quality control) Immunoassay Controls Lot 160275 Expiration date: 12-2017 b. FREND PSA Plus test cartridges Lot 306017 Expiration date: 06-12-2017 c. 0.9% NaCl Lot 306017 Expiration date: 06-01-05 2. An interview with the primary testing person at 11:45 hours in the laboratory confirmed the findings. She revealed that the laboratory has never performed PSA (prostate specific antigen) testing and did not know why the items had not been discarded. Key: % - percent sign NaCl - Sodium Chloride
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Review of verification studies found that the laboratory failed to ensure that each system introduced had been validated to ensure it met the manufacturer's specifications prior to testing patients. The findings were: 1. Review of laboratory records revealed the facility did not have verification records available for review to ensure the laboratory verified the accuracy, precision, reportable range, and normal patient ranges for the Sysmex-XP hematology analyzer. 2. An interview with the primary testing person on September 25, 2018 at 15:15 hours in the laboratory confirmed the findings. She revealed that the verification was done, but she could not find the verification study.
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 direct observation, review of manufacturer's instructions, and confirmed in interview of facility personnel, the laboratory failed to perform maintenance procedures as required by the manufacturer. The findings were: 1. Direct observation made in the laboratory during the initial tour of the laboratory at 10:15 hours revealed the Sysmex XP-300 hematology analyzer had blood splatters across the front of the analyzer. 2. Review of the manufacturer's instructions for Sysmex XP-300 (AU553517, May 2014) under Chapter 12 Cleaning and Maintenance it stated, "Weekly Maintenance: Clean the SRV tray, Monthly or Every 1500 Samples Maintenance: Clean the Waste Chamber, and 3 Month Maintenance or Every 4500 Samples: Clean the SRV. 3. Review of laboratory records from October 2017 to August 2018 revealed no instrument maintenance records available for review that would provide documentation that the laboratory was performing the maintenance procedures as required by the manufacturer. 4. An interview with the primary testing person on September 25, 2018 at 16:00 hours in the laboratory confirmed the findings. She revealed that she performs maintenance but did not know it needed to be documented.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: A. Based on review of quality control records, review of patient results, and interview of facility personnel it was revealed that the laboratory failed to have a quality control procedure that established the number and frequency of controls that could detect immediate errors. The findings were: 1. According to the primary testing person on September 25, 2018 at 12:15 hours in the laboratory, the laboratory runs three levels of controls and all three levels have to be within range for acceptability. When asked if the laboratory had a policy that defined this practice, she stated, "No." 2. Random review of quality control records from October 2017 to August 2018 revealed the facility failed to ensure 3 levels of quality control were within range each day of patient prior to testing patients: April 2, 2018 The low control was run under the wrong file. Therefore, no abnormal high control was performed. The laboratory did not ensure 3 levels of control were acceptable prior to testing patients. July 19, 2018 The platelet count for abnormal low was out of range. The laboratory did not ensure 3

	levels of control were acceptable prior to testing patients. 3. Review of patient records revealed 11 patients were tested on April 2, 2018 and 13 patients on July 19, 2018 when 3 levels of controls were not within acceptable range (see patient alias list). 4. An interview with the primary testing person on September 25, 2018 at 16:00 hours in the laboratory confirmed the findings. B. Based on a review of quality control records and interview of facility personnel it was revealed that the laboratory failed to have a quality control procedure that monitored the accuracy and precision of the Sysmex-XP 300 hematology quality control over time. The findings were: 1. A review of the hematology control records for the Sysmex XP-300 hematology analyzer from 2017 and 2018 revealed no evidence the controls were being monitored for shifts, trends, precision or accuracy using either the Levy-Jennings graphs printed by the instrument, evaluation of monthly control standard deviation and coefficient of variation of each parameter, peer group data or any other means. 2. An interview with the primary testing person on September 25, 2018 at 14:30 hours in the laboratory confirmed the findings. She revealed that she performed three levels of daily control, but did not print or perform any other quality control review.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor observation in the laboratory, the Sysmex 300 quality control package insert, surveyor observation, quality control records, and staff interview, it was revealed the laboratory failed to provide documentation of establishing quality control target ranges. The findings were: 1. This is a repeat deficiency from the survey dated November 1, 2016. 2. At 1405 hours in the laboratory, the surveyor requested the instructions for use for the Sysmex XP-300 EightCheck-3WP X-TRA. The laboratory provided the document which was dated, "Rev. 15, /2/2013." 3. A review of the Sysmex EIGHTCHECK-3WP X-TRA e-Check quality control package insert (Rev. 15, 02/2013) under the section "QC Targets" revealed: "Assay means are not intended for use as analyzer QC file target values. For effective QC, each laboratory should set its own target values. Sysmex recommends that each laboratory establish this QC target value by collecting at least 10 data points per control level over 5 days. The mean QC target values from this initial data collection should be within the expected ranges listed on the package insert. Sysmex recommends as an option that each laboratory either establish their own QC file limits based on the laboratory's historical coefficient of variation (CV) by using historical data or by using the limits provided in the package insert with each lot of EIGHTCHECK-3WP X-TRA." 4. At 1405 hours in the laboratory, the surveyor requested to be shown the target QC

	(quality control) values for lot number 8227070 (the most recent lot number) and lot numbers 814307, 805907, and 734007. No documentation was provided. 5. The laboratory failed to have a policy regarding how to establish quality control target ranges for CBC (complete blood count). 6. A review of quality control records from July 2017 to August 2018 revealed 7 lot number changes. The laboratory did not establish their own target values for any of the following lot numbers: Lot No. 708807 717207 725607 734007 805907 814307 822707 7. An interview with the primary testing person on September 25, 2018 at 14:45 hours confirmed the findings. She stated the laboratory uses the manufacturer's ranges but that sometimes the person before her forgot to change the ranges.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on direct observations, review of laboratory policy, review of quality assessment records and confirmed in interview of facility personnel, the laboratory failed to establish written policies to identify and correct problems in its analytic systems as evidenced by: 1. The laboratory failed to follow the manufacturer's instructions to ensure flags are resolved prior to their release to the healthcare provider (refer to D5411-A). 2. The laboratory failed to follow the manufacturer's instructions for BD (Becton Dickinson) blood collection tubes to ensure tubes are adequately filled (refer to D5411-B). 3. The laboratory failed to monitor room temperature, room humidity, and and refrigerator conditions as required by the manufacturer (refer to D5413). 4. The laboratory failed to ensure reagents were properly labeled with identification, concentration, storage requirements, and dates (refer to D5415). 5. The laboratory failed to monitor revised quality control expiration dates on Sysmex XP-300 quality control reagents (refer to D5417). 6. The laboratory failed to provide documentation of a verification study for the Sysmex XP-300 hematology analyzer (refer to D5421). 7. The laboratory failed to provide documentation of performing required manufacturer maintenance procedures (refer to D5429). 8. The laboratory failed to have a policy for establishing quality control procedures to detect immediate errors and errors over time (refer to D5441). 9. The laboratory failed to provide documentation of establishing its own target values for new lots of quality controls on the Sysmex XP-300 (refer to D5469).
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on direct observations, review of manufacturer's instructions, review of quality control records, review of patient records, review of environmental records, and

	confirmed in interview of facility personnel, the laboratory director failed to provide overall management of the laboratory (refer to D6013, D6016, D6018, D6020, D6021, D6029, D6030, D6031, D6032).
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on review of laboratory records and confirmed in interview of facility personnel, the laboratory director failed to ensure a verification study was performed to ensure the accuracy and precision of the Sysmex XP-300 (refer to D5421).
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute (API) proficiency testing records, review of instrument printouts, and confirmed in interview of facility personnel, the laboratory director failed to ensure proficiency testing samples were tested the same as patient samples (refer to D2006).
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by:

	Based on review of the laboratory's American Proficiency Institute (API) proficiency testing records, and confirmed in interview of facility personnel, the laboratory director failed to review 1 of 5 proficiency test events (refer to D5211).
D6020	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 the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on direct observations, review of laboratory policy, review of manufacturer's instructions, review of quality control records, review of patient records, and confirmed in interview of facility personnel, the laboratory director failed to have a policy to establish and maintain a quality control plan (refer to D5441 and D5469).
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: Based on direct observations, review of laboratory policy, review of environmental records, review of patient records, review of manufacturer's instructions, and confirmed in interview of facility personnel, the laboratory director failed to have a policy that established and maintained a quality assurance plan (refer to D5391 and D5791).
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by:

	Based on review of the submitted CMS Form 209, review of personnel records, and confirmed in interview of facility personnel, the laboratory director failed to ensure that prior to testing patients, each testing person had the appropriate education and training to perform moderate complexity testing in hematology. The findings were: 1. Review of the laboratory's submitted Form CMS-209, approved by the laboratory director on September 25, 2018, revealed the laboratory director identified 4 testing persons. 2. At 11:45 hours and 13:25 hours on September 25, 2018, the facility was asked to provide education and training records for each of the testing persons listed on the Form CMS-209. No records were made available for review. 3. An interview with the primary testing person on September 25, 2018 at 13:25 hours in the laboratory confirmed the findings. She revealed that the person who had personnel records, "Was not there today, and we don't have access to those records." 4. An interview with the office manager in the office on September 25, 2018 at 13:30 hours confirmed the findings. She stated, "They would have to bring education records in, we don't have those." Key: CMS - Centers for Medicare and Medicaid Services
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) 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: Based on review of laboratory records, and confirmed in interview of facility personnel revealed the laboratory director failed to establish policies and procedures for competency testing. The findings were: 1. Review of laboratory records revealed the laboratory did not have a policy or procedure for evaluation of competency. 2. Review of personnel records revealed no competency no twice annual or annual competency assessments were available for review as of the completion of the survey on September 25, 2018. 3. An interview with the primary testing person on September 25, 2018 in the laboratory at 11:45 hours confirmed the findings. She revealed that the laboratory does not have a policy manual. She went on to say that the laboratory director has observed her work, but that nothing was documented.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;

	This STANDARD is not met as evidenced by: Observations, review of manufacturer's instructions, policies and procedures, patient test records and interview of facility personnel found that the laboratory director failed to ensure that an approved written procedures was available to all testing personnel testing patient specimens (refer to D5411, D5415, D5417, D5429, D5441, and D5469).
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of personnel records, and confirmed in interview of facility personnel revealed the laboratory director failed to specify in writing the responsibilities and duties of each testing person to determine if supervision was required. The findings were: 1. Review of personnel records revealed the laboratory did not have job descriptions available for each role required for a moderate complexity laboratory: laboratory director, clinical consultant, technical consultant, and testing person. 2. In an interview of the primary testing person on September 25, 2018 in the laboratory at 13:25 hours she revealed that she was verbally told her responsibilities. She could not provide a job description.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on direct observations, review of manufacturer's instructions, review of quality control records, review of patient records, review of environmental records, and confirmed in interview of facility personnel, the technical consultant, who is also the laboratory director, failed to provide technical oversight of the laboratory (refer to D6036, D6040, D6042, D6044, D6053, and D6054).
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the

	laboratory. This STANDARD is not met as evidenced by: Based on direct observations, review of manufacturer's instructions, review of quality control records, review of environmental records, review of patient records, review of environmental records, and confirmed in interview of facility personnel, the technical consultant, who is also the laboratory director, failed to provide technical and scientific oversight of the laboratory (refer to D5411, D5415, D5417, D5429, D5441, and D5469).
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on review of laboratory records and confirmed in interview of facility personnel, the technical consultant who is also the laboratory director failed to ensure a verification study was performed to ensure the accuracy and precision of the Sysmex XP-300 (refer to D5421).
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on a review of quality control records, quality assurance records and staff interview, it was revealed that the technical consultant (who is also the laboratory director) failed to ensure an appropriate quality control program was maintained throughout the testing process (refer to D5441, D5469).
D6044	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(6) (b) The technical consultant is responsible for-- (b)(6) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly; This STANDARD is not met as evidenced by: Based on review of laboratory policy, review of manufacturer's instructions, review of patient records, and confirmed in interview of facility personnel, the technical consultant, who is also the laboratory director, failed to ensure corrective action for

	flags on CBCs (complete blood count) are resolved prior to their release to the healthcare provider (refer to D5411-A).
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 laboratory's submitted Form CMS-209, review of personnel records, and confirmed in interview of facility personnel, the technical consultant, who is also the laboratory director, failed to perform twice annual competency assessments on 1 of 4 testing persons. The findings were: 1. Review of personnel records provided by the facility revealed testing person 2 (as listed on Form CMS-209) began patient testing on April 8, 2017. 2. Further review of the laboratory's personnel records revealed no competency assessments were available for review that the technical consultant performed during the testing person's first year of patient testing. 3. As of the date of the survey, September 25, 2018, testing person 2 (as listed on Form CMS-209) should have had two competency assessments available for review. 4. An interview with the primary testing person on September 25, 2018 at 13: 25 hours in the laboratory confirmed the findings. She revealed that the person who had personnel records, "Was not there today, and we don't have access to those records." Key: CMS - Centers for Medicare and Medicaid Services
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 laboratory's submitted Form CMS-209, review of personnel records, and confirmed in interview of facility personnel, the technical consultant, who is also the laboratory director, failed to perform annual competency assessments on 1 of 4 testing persons who required one. 1. Review of personnel records provided by the facility revealed testing person 3 (as listed on Form CMS-209) had a start date of January 1, 2003. 2. Further review of the laboratory's personnel records revealed no annual competency assessments were available for review that the technical consultant performed on testing person 3 (as listed on Form CMS-209). 3. As of the date of the survey, September 25, 2018, testing person 3 (as listed on Form CMS-209) should have had an annual competency assessment in 2017 available for review. 4. An interview with the primary testing person on September 25, 2018 at 13:25 hours in the laboratory confirmed the findings. She revealed that the person who had personnel records, "Was not there today, and we don't have access to those records."
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421

	The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of education to qualify 4 of 4 testing personnel (refer to D6065).
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's personnel files, and staff interview, it was revealed the laboratory failed to have documentation of education to qualify 4 of 4 testing personnel to perform moderate complexity testing. The findings were: 1. A review of the laboratory's submitted Form CMS 209 (signed by the laboratory director on 09/25/2018) revealed the laboratory identified 4 testing personnel. 2. A review of the laboratory's personnel records revealed 4 of 4 testing personnel records were not available for review to qualify them to perform moderate complexity testing. 3. An interview with the primary testing person on September 25, 2018 at 13:25 hours in the laboratory confirmed the findings. She revealed that the person who had personnel records, "Was not there today, and we don't have access to those records." 4. An interview with the office manager (not identified on the Form CMS-209) in the office on September 25, 2018 at 13:30 hours confirmed the findings. She stated, "They would have to bring education records in, we don't have those." Key: CMS - Centers for Medicare and Medicaid Services