Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2120328	06/26/2018
Name of Provider or Supplier	**Street Address, City, State**	
Caprock Cath Lab, Lp	4324 23rd Street, Lubbock, 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	The laboratory was surveyed and failed to meet the following conditions of the CLIA regulations found at CFR 42 493.1 through 493.1780: D2000 - 42 C.F.R. 493.801 Condition: Enrollment and testing of [proficiency testing] samples; D5024 - 42 C.F.R. 493.1215 Condition: Hematology; D5024 - 42 C.F.R. 493.1240 Condition: Preanalytic 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. 493.1421 Condition: Laboratories performing moderate complexity testing; testing personnel; The laboratory's failure to be in compliance with these regulations was found to pose IMMEDIATE JEOPARDY to the patients served by the laboratory.
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Review of the CMS report 155 , laboratory records and interview of facility personnel found that the laboratory failed to enroll in a CMS approved proficiency testing program for Hematology for the analytes Prothrombin time, INR and Activated Thromboplastin Time(ACT). The Findings included: 1. Review of the CMS report 155 found no scores for the Prothrombin Time, INR and ACT in 2016, 2017 or 2018.

	2. Review of laboratory records found no documentation that the laboratory enrolled or participated in a proficiency testing program for the Specialty of Hematology or had another means of verifying the accuracy of results for the Prothrombin Time, INR and ACT . 3. Interview of Testing person 8 on the CMS Report 209 conducted on June 25, 2018 ay 09:54 AM confirmed that the laboratory failed to enroll in a proficiency testing program for Prothrombin Time/ INR and ACT.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Review of laboratory records and interview of facility personnel found that the laboratory failed to retain quality control and patient test records for all specimens tested on the Abbott i-STAT serial number 388143 between November 2016 and August 2017 Findings included: 1. Review of laboratory records found that the laboratory failed to retain instrument printouts for quality control and patient specimens tested on the Abbott i-STAT. The laboratory documented that the Abbott i-STAT serial number 388143 used for testing between November 2016 and August 2017 was no longer working on August 24, 2017. I-STAT serial number 389195 was received on August 29, 2018. 2. Interview of testing personnel conducted on June 25, 2018 at 3:45 PM confirmed that instrument printouts were not retained. Patient results were recorded in the patient's chart and they have no means of retrieving testing information from the previously used Abbott i-STAT serial number 388143 .
D5024	HEMATOLOGY CFR(s): 493.1215 If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493. 1281 through 493.1299. This CONDITION is not met as evidenced by: Review of personnel files, laboratory records, Abbott i-STAT systems manual, quality control records and interview of facility personnel found the laboratory failed to meet the requirements for the specialty of Hematology. Findings Included: 1. The laboratory failed to have a written policy to assess the competency of the technical consultant or testing personnel. (See D5209) 2. The laboratory failed to follow the manufacturer's instructions for the collection of patient specimens used to test PT/INR on the Abbott iSTAT 300 analyzer. (see D5311) 3. Laboratory failed to have a procedure available to testing personnel that had been approved signed and dated by the current laboratory director. (See D5407) 3. The laboratory failed to define and monitor the proper temperature and humidity consistent with the manufacturers' instructions for operation of the Abbott i-STAT. (See D5413) 4. The Laboratory failed to establish and maintain a quality control program for the iSTAT . (See D5441) 7. The laboratory failed to establish written policies and procedures (Quality Assurance) for an ongoing mechanism to monitor, assess and correct problems identified in the hematology preanalytic, analytic and postanalytic systems for testing on the Abbott

	iSTAT before, during and after verification in order to ensure accurate patient results. (See D 5391, D5791)
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on a review of policies and procedures, personnel records, and interview of facility personnel it was revealed that the laboratory failed to have a procedure to assess the competency of the technical consultant and testing personnel . Findings included: 1. A review of policies and procedures found no written policy for assessing the competency of all supervisors, consultants and testing personnel. 2. Review of personnel files found no documentation of competency assessments performed for 8 of 8 testing personnel. 3. Interview of testing person 8 conducted on June 25, 2018 at 09:48 AM confirmed there was no procedure for assessing the competency of the technical consultant or testing personnel.
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, 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 preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on a review of laboratory temperature records, quality assurance records, and interview of laboratory personnel, it was revealed that the laboratory did not meet the applicable preanalytic system(s) requirements and failed to monitor and evaluate the quality of all preanalytic systems. 1. The laboratory failed to follow manufacturer's instructions for the collection and preparation of samples to be tested for Prothrombin Time/ INR using the Abbott iSTAT. (Refer to D5311) 2. Failure of the laboratory to monitor the quality of the preanalytic phase of all testing processes (refer to D5391) caused the laboratory to be unable to identify and correct all preanalytic problems.
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: A review of policies and procedures, the CMS report 116 completed by the facility, observations, review of the manufacturer's operator's Guide and interview of facility personnel found that the laboratory failed to follow the manufacturer's instructions for the collection and testing of patient specimens for PT/INR using the Abbot iSTAT 300 analyzer. Findings included: 1. Review of policies and procedures found the laboratory failed to have a written procedure available to testing personnel for use in testing of patient specimens for PT/INR using the Abbot iSTAT 300 analyzer. 2. Review of the CMS report 116 provided by the faciity found that the laboratory recorded an annual test volume of 26,292 Hematologoy procedures. A patient test list was requested but not provided. 3. Observations made during the tour of the facility found that the laboratory had only Becton Dickinson Vacutainer tubes with Lithium Heparin available to testing personnel (in the procedure room) for the collection of patient specimens that were not tested using fresh whole blood. 4. Review of the manufacturer's Instructions for use for the PT/INR found on page 2 under the heading Intended Use - The iSTAT PT, a prothrombin Time test , is useful for monitoring patients receiving oral anticoagulant therapy such as Coumadin or Warfarin." Further review of the manufacturer's instructions for use found on page 6 under the heading "Factors affecting Results- The presence of exogenously added heparin, citrate, oxalate, or EDTA from blood collection devices will interfere with test results." Continued review found on page 7 under the heading Specimen Collection and preparation - "Caution: The iSTAT PT/INR cartridge is designed to accept a a sample between 20 and 45 micrometers. A single drop of blood from either a finger puncture or as formed at the tip of a syringe will typically be within this range. Venipunctures - The sample for testing should be drawn into a plastic collection device (either a plastic syringe or plastic evacuated tube). The collection device cannot contain anticoagulants such as heparin, EDTA, oxalate, or citrate. The collection device cannot contain clot activators or serum separators. The sample should be immediately dispensed into the sample well of a cartridge." 5. Interview of testing person 8 on the CMS report 209 Laboratory Personnel Report conducted on June 25, 2018 at 11:02 AM found that the laboratory performed the PT/INR and the Chem 8 + tests using specimens collected in the BD Vacutainer green top collection tube containing Lithium Heparin. She was asked to detail her collection and testing again at 2:40 PM and provided the following verbal procedure: "From the IV (initial stick) I attach a 10 cc syringe and hand it off to a second person in the procedure room to inject into the green top tube. I then use a 3 cc syringe to remove 1cc of blood from the green top tube, attach a blunt tip needle to the syringe and introduce blood into the PT/INR cartridge, and wait for results to complete. Once completed, a second 3cc syringe with needle is used to remove 1 cc of blood from the green top tube, attaching a new blunt tip needle to inoculate the Chem 8+ cartridge and then allow to test." Interview of testing person 7 on the CMS report 209 conducted on June 25, 2018 at 2:44 PM agrees that she would use the same procedure as Testing person 8.
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 review of laboratory policies and procedures, surveyor observations, patient test records, and confirmed in interview with staff, the laboratory failed to have a quality assessment policy to to monitor, assess, and correct problems identified in the preanalytic systems. (see D5311)
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: Review of the Abbott iSTAT operator's guide, policies and procedures and interview of facility personnel found that the laboratory failed to have an approved procedure manual available to testing personnel for the performance of Activated Clotting Time (ACT) and Prothrombin Time/INR using the Abbott iSTAT. The Findings included: 1. Review of the Abbott iSTAT Operator's Guide found no documentation of approval by the laboratory director. 2. Review of policies and procedures found no additional written policy/procedure available to testing personnel for using the iSTAT. 3. Interview of testing person 8 on the CMS report 209 Laboratory Personnel Report conducted on June 25, 2018 at 10:00 AM confirmed that the laboratory did not have an approved procedure for the use of the iSTAT other than the operator's Guide.
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: Observations, review of laboratory records and interview of facility personnel found that the laboratory failed to ensure that patient testing supplies and equipment were stored at the appropriate temperature to ensure proper operation and prevent degradation of the products. The findings included: 1. Observations made during the tour of the facility found no means of monitoring the temperature of the procedure room where the iSTAT analyzer and cartridges, and specimen collection tubes were kept available for use in patient testing. 2. Review of laboratory records found no documentation of the temperature of the procedure room where the iSTAT analyzer and cartridges, and specimen collection tubes were kept available for use in patient testing. 3. Interview of testing person 8 on the CMS report 209 Laboratory Personnel Report conducted on June 25, 2018 at 10:30 AM confirmed that the laboratory did not monitor and document the temperature of the procedure room.
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:
Based on observations, review of laboratory policies and procedures, manufacturers instructions, verification records records, patient test records and staff interview, the laboratory failed to follow the manufacturers instructions to ensure that accuracy, precision, reportable range met the manufacturers specifications on the Abbott iSTAT using the prothrombin time/INR and ACT cartridges before testing patient samples. The findings included: 1. Observations made during the tour of the laboratory found that the laboratory was using the Abbot iSTAT serial number 388143 for testing patient specimens using the non-waived prothrombin time/INR and ACT cartridges and the waived Chem 8+ cartridges. 2. Review of policies and procedures found that the laboratory was using the operators guide for the Abbot iSTAT as the procedure for use by testing personnel. 3. Review of the manufacturers instructions for prothrombin time/INR found: a. on page 2 under the heading Expected Values: Prothrombin Time (PT//INR) verified clinical range 0.9 to 6.0* *the performance characteristics of the iSTAT PT/INR measurement have not been established at INR's above 6.0 b. Performance Characteristics the typical performance data summarized below were collected in healthcare facilities by healthcare professionals trained in the use of the iSTAT system and comparative methods. Imprecision - initial studies were conducted to collect imprecision data for venous and capillary whole blood samples. Imprecision data for venous whole blood samples were collected in duplicate at two clinical sites. Imprecision data for capillary whole blood samples were collected in duplicate at one clinical site using a single capillary stick. Site one (Venous) -percent coefficient of variation was 4.7% using 181 samples. Site two (venous) - percent coefficient of variation 4.0% using 102 samples. Site three (capillary) - percent coefficient of variation 4.6% using 33 samples. c. On page 3 under the heading Reference Intervals - in a study to determine a reference interval for PT/INR, Venus samples from healthy volunteers were collected in plastic tubes, and whole blood was analyzed with one lot of cartridges on the iSTAT system. Capillary samples were obtained from the same volunteers using soft click Pro (setting of 3) and analyzed on the same cartridge lot. Reference intervals for INR in venous and capillary samples were determined according to the CLSI guideline C 28-A2 the data for reference ranges (INR) for venous whole blood was 0.8 to 1.2 and for capillary whole blood was 0.8 to 1.2. Due to the many variables that may affect PT/INR results, each laboratory should establish its own reference interval. d. Method Comparison - method comparisons will vary from site to site due to differences in the sample handling, reagent and instrument systems in use and other site-specific variables. A correlation study should be performed to establish differences between the iSTAT PT/INR measurement and other methods used." 2. Review of the verification studies provided for the i STAT system using instrument serial number 388143 and the Kaolin ACT cartridges and the PT/INR cartridges found that the laboratory had no documentation available for review to demonstrate that the Abbott iSTAT had been evaluated for accuracy, precision, reportable range, and verification of patient normal ranges. The laboratory's verification studies consisted of two levels of quality control specimens tested by the Abbott point-of-care representative as follows: a. Kaolin ACT - ACT control level

	one lot 261074 was tested 20 times on November 9, 2016 between 00:35 AM and 18: 30 PM. And control level two lots 27107 was tested 20 times on November 9, 2016 18 times between 00:42 AM and 18:18 PM. b. PT/INR - PT/INR control level one lot 281074 was tested 20 times between 00:04 AM and 17:47 PM and control level 2 lots 291075 was tested 20 times between 00:16 AM and 17:58 PM. Abbott I STAT serial number 389195 was received on August 29, 2017. No verification studies were available for review. There were no patient specimens used in the verification study completed on November 9, 2016. The results of controls used in the verification study were not evaluated to determine acceptability. 3. Review of patient test records found that the laboratory tested 57 patient specimens for ACT and 35 patient specimens for prothrombin time/INR between August 2017 and June 25, 2018 without verifying the iSTAT system. There was no means to determine how many patient specimens were tested prior to August 31, 2017. 4. Interview of testing person eight listed on the CMS report 209 conducted on June 25, 2018 at 10 AM confirmed there were no additional verification studies available for review to determine if the I STAT met the manufacturers claims for accuracy, precision and other specifications.
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: Interview of facility personnel, observations and review of laboratory records found that the laboratory failed to test at least two levels of quality control material each day of patient testing when using the iSTAT to test patients for PT/INR and the Kaolin Activated Clotting Time (ACT-K) or developing an individualized Quality control Plan (IQCP). The findings included: 1. Interview of testing person one on the CMS Report 209 Laboratory Personnel Report conducted on June 25, 2018 at 3:58 PM confirmed that the laboratory did not test two levels of quality control materials each day of patient testing for Prothrombin Time. She went on to say that they tested quality control materials when opening each new box of cartridges. She went on to confirm that quality control records and patient test records for samples tested prior to August 2017 were not available for review because the laboratory did not retain instrument printouts or document the results using patient test logs. She stated that they were able to retrieve results from the iSTAT if needed, but had received a "new" iSTAT when the original analyzer failed in August 2017. Patient test records for patient specimens tested between November 2016 and August 31, 2017 were not kept by the facility. PT/INR 2. Observations made during the tour of the facility found that the laboratory had one box each of iSTAT PT/INR level 1 Control lot 281092 expiration 2018-08-31, iSTAT PT/INR level 1 Control lot 281097 expiration 2019-01-31 and iSTAT PT/INR level 2 Control lot 291093 expiration 2018-09-30 available for testing / PT/INR cartridges in the refrigerator used to store cartridges and quality

control materials. 3. Review of laboratory records found documentation of two levels of quality control tested for Prothrombin Time/ PT/ INR on the following dates: Control level 1 lot 281074 Expiration 2017/02/28 and Control level 2 lot 291075 expiration 2017/03/31 were tested as follows: November 14, 2016 November 21, 2016 November 28, 2016 December 7, 2016 December 14, 2016 December 19, 2016 December 27, 2016 January 3, 2017 January 10, 2017 Control level 1 lot 281074 Expiration 2017/02/28 was tested on 4 dates between January 17, 2017 and February 27, 2017 without documentation of a second control: January 17, 2017 January 30, 2017 February 6, 2017 February 27, 2017 Control level 1 281092 expiration 2018-08-31 and control level 2 lot 291093 expiration 2018-09-30 were tested on June 21, 2018. Control level 1 lot 281074 Expiration 2017/02/28 was tested on five dates after its expiration between March 1, 2017 and April 3, 2017 without a second level of quality control material being tested. March 7, 2017 March 13, 2017 March 22, 2017 March 28, 2017 April 3, 2017 Control level 1 lot 281079 Expiration 2017/07/31 and level 2 lot 291080 Expiration 2017/08/31 were both tested between June 12, 2017 and November 22, 2017 as follows: June 12, 2017 June 19, 2017 June 26, 2017 July 5, 2017 July 10, 2017 July 19, 2017 July 24, 2017 August 1, 2017 August 8, 2017 August 21, 2017 August 29, 2017 August 30, 2017 September 5, 2017 September 11, 2017 September 18, 2017 September 26, 2017 October 2, 2017 October 9, 2017 October 16, 2017 October 23, 2017 November 13, 2017 November 22, 2017 4. Review of patient test records between August, 2017 and June 25, 2018, found that the laboratory tested 35 patient samples for Prothrombin Time on the following days without testing at least two levels of quality control materials to ensure the accuracy of results. August 31, 2017 - patient 54010 and 14340 September 6, 2017 - patient 27330 September 13, 2017 - patient 101030 September 15, 2017 - patient 14200 September 19, 2017 - patient 9960 October 10, 2017 - patient 80270 and patient 31890 October 11, 2017 - patient 89920 October 12, 2017 - patient 12070 October 17, 2017 - patient 110020 October 19, 2017 - patient 114010 October 21, 2017 - patient 110780 October 25, 2017 - patient 1960 and patient 3830 October 26, 2017 - patient 24800 and patient 110780 October 30, 2017 - patient 35920 November 9, 2017 - patient 110780 December 1, 2017 - patient 40710 December 8, 2017 - patient 37220 December 13, 2017 - patient 108550 December 21, 2017 - patient 1680 January 18,2018 - patient 121070 and patient 104990 February 15, 2018 - patient 14900 March 8, 2018 - patient 124340 March 19, 2018 - patient 7540 April 14, 2018 - patient 127560 April 17, 2018 - patient 127830 May 21, 2018 - patient 3700 June 7, 2018 - patient 3700 June 12, 2018 - patient 20410 June 13,2018 - patient 66270 tested at 3:22 and 3:45 There were no patient test records available to review for patients tested prior to August 31, 2017. ACT-K 2. Observations made during the tour of the facility found that the laboratory currently had 2 boxes of ACT level 1 (one box each lot 261094 expiration 2018-10-31 and lot 261096 expiration 2018-12-31) and 12 boxes control level 2 lot 271092 expiration 2018-08-31 available for testing ACT/K cartridges, in the refrigerator used to store cartridges and quality control materials. 3. Review of laboratory records found documentation of two levels of quality control tested for ACT/K on the following dates: Control level 1 lot 281074 Expiration 2017 /02/28 and Control level 2 lot 291075 expiration 2017/03/31 were tested as follows: November 14, 2016 November 21, 2016 November 28, 2016 December 7, 2016 December 14, 2016 December 19, 2016 December 27, 2016 January 3, 2017 January 10, 2017 Control level 1 lot 281079 Expiration 2017/07/31 and level 2 lot 291080 Expiration 2017/08/31 were both tested between June 12, 2017 and November 22, 2017 as follows: June 12, 2017 June 19, 2017 June 26, 2017 July 5, 2017 July 10, 2017 July 19, 2017 July 24, 2017 August 1, 2017 August 8, 2017 August 21, 2017 August 29, 2017 August 30, 2017 September 5, 2017 September 11, 2017 September 18, 2017 September 26, 2017 October 2, 2017 October 9, 2017 October 16, 2017

	October 23, 2017 November 13, 2017 November 22, 2017 4. Review of patient test records between September 2017 and October 2017 and June 2018, found that the laboratory tested 57 patient samples for ACT-AK on the following days without testing at least two levels of quality control materials to ensure the accuracy of results. September 6, 2017 - Patient 95680 and patient 53600 tested twice - at 21:27 and 22:10 September 12, 2017 - patient 101550 and patient 86770 September 13, 2017 - patient 98640 and patient 101030 September 14, 2017 - patient 58050 September 15, 2017 - patient 14160 September 19, 2017 - patient 8110, patient 19820 and patient 72390 September 21, 2017 - patient 13240 and patient 14160 September 22, 2017 - patient 109030 October 5, 2017 - patient 87500 October 6, 2017 - patient 30420 and patient 12720 October 7, 2017 - Patient 40430, patient 25420 and patient 112520 October 10, 2017 - Patient 5730 and patient 42760 October 11, 2017 - patient 31890 and Patient 89920 October 12 ,2017 - patient 110140 October 13, 2017 - Patient 103490 and patient 30420 October 14, 2017 - Patient 14990 and patient 5060 October 19, 2017 - Patient 85460 and patient 12180 October 20, 2017 patient 106050 and patient 72760 October 24, 2017 patient 410 and patient 82870 October 25, 2017 - patient 36780, patient 36780 tested at 3:39, 05:02, 05:32 and 14:20 October 30, 2017 - patient 108340 October 31, 2017 - patient 14860, patient 97640 June 2, 2018 - Patient 19890 tested at 01:00, 02:06 and 02:44 June 7, 2018 - -patient 3700 tested at 21:48 and 22:16 and patient 123630 June 8, 2018 - Patient 123630 tested at 00:29 and 01:11 June 9,2018 - patient 132810 June 13, 2018 - patient 4600 at 20:55 and 21:14 June 20, 2018 - patient 34820 There were no patient test records available to review for patients tested prior to August 31, 2017.
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: Review of personnel files, laboratory records, Abbott i-STAT systems manual, quality control records and interview of facility personnel found the laboratory failed to establish a quality assessment program to identify and correct problems in hematology. Findings Included: 1. Laboratory failed to have a procedure available to testing personnel that had been approved signed and dated by the current laboratory director. (See D5407) 2. The laboratory failed to define and monitor the proper temperature and humidity consistent with the manufacturers' instructions for operation of the Abbott i-STAT. (See D5413) 3. The Laboratory failed to establish and maintain a quality control program for the iSTAT . (See D5441)
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 review of laboratory policies and procedures, quality control records, patient test records, and confirmed in interview with laboratory staff, the Laboratory Director failed to provide overall management and direction to the laboratory. 1. The laboratory Director failed to ensure that verification procedures used to verify the performance specifications for the Abbott iSTAT were adequate to determine accuracy , precision and other performance specifications. (see D 6013) 2. The laboratory Director failed to ensure that testing personnel were performing test methods as required. (see D 6014) 3. The laboratory Director failed to ensure that the laboratory was enrolled in an HHS (Health and Human Services) approved proficiency testing program for Hematology. (see D 6015) 4. The laboratory Director failed to ensure that a quality control program had been established and maintained to ensure the accuracy and reliability of results obtained when using the Prothrombin Time/INR tested on the Abbott iSTAT . (See D 6020) 5. The laboratory Director failed to ensure that a Quality Assessment program had been established to ensure the quality of results obtained when using the Abbott iSTAT to test Prothrombin Time /INR, and the Activated Clotting Time. (See D 6021) 6. The laboratory Director failed to ensure that Testing personnel had received the appropriate education and training prior to performing non waived testing. (See D 6028) 7. The laboratory Director failed to ensure that procedures had been established to assess the competency of individuals performing moderate complexity procedures. (see D6030) 8. The laboratory Director failed to ensure that an approved procedure manual was available to all testing personnel responsible for patient testing. (see D 6031) 9. The laboratory Director failed to specify in writing the duties of each consultant, supervisor and testing person. (See D 6032)
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: The laboratory director failed to ensure that verification procedures used to verify the performance specifications for the Abbott iSTAT were adequate to determine accuracy, precision and other performance specifications prior to testing patient specimens. (See D 5423)
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(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)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results.

	This STANDARD is not met as evidenced by: The laboratory director failed to ensure that testing personnel were collecting and testing patient specimens as required by the manufacturer when using the Abbott iSTAT for testing ACT and prothrombin time/INR. (See D5311 and D5411)
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview of facility personnel found that the laboratory director failed to ensure the laboratory was enrolled in a proficiency testing program for Hematology. (See D2000)
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 observations, review of quality control records, patient test records and interview of facility personnel the laboratory director failed to establish and maintain the quality control program for PT/INR and ACT using the Abbott iSTATsystem. The laboratory failed to test at least two levels of quality control materials each day of patient testing or develop an Individualized Quality Control Plan (IQCP) to reduce the frequency and quality control testing. (see D 5441)
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 review of the laboratory's policies and staff interview, it was revealed the laboratory director failed to ensure quality assessment programs were established and maintained to assure the quality of laboratory testing. (see D5391 and D5791).
D6028	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(10) 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)(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart; This STANDARD is not met as evidenced by: Review of personnel files, laboratory test records, patient test records and interview of facility personnel found that the laboratory director failed to ensure that one of eight testing personnel performing Hematology testing had the appropriate education and training for performing non waived procedures. (see D 6065 and D 6066)
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: Review of laboratory records and interview of facility personnel found that the laboratory director failed to ensure that testing personnel met the minimum education requirements and received appropriate training prior to testing patient specimens using the Cell Dyn Emerald hematology analyzer. Findings included: 1. Review of laboratory records and personnel records found no documentation of education or training for one of eight testing personnel listed on the CMS report 209 laboratory personnel report . Testing person three (hire date March 2017) had no documentation of education or training available for review. 2. Interview of the practice administrator and the testing person eight conducted on June 25, 2018 at 9:48 AM confirmed that education records and documented training for one of eight testing personnel were not available for review.
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: The Laboratory director failed to ensure that the laboratory had a procedure to assess the competency of all testing personnel and the technical consultant responsible for patient testing to include Direct Observation,Monitoring the recording and reporting of test results,Review of quality control and proficiency testing, instrument maintenance, Assessment of test performance , and Assessment of problem solving skills. (See D 5209)
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: Based on review of the laboratory's policies and procedures, review of the manufacturer's instructions for the Abbott iSTAT , and staff interview, it was found that the laboratory director failed to ensure that a written procedure was available to all testing personnel outlining the step by step performance of the test. (see D 5407)
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: Review of personnel records, policies and procedures and interview of facility

	personnel found that the laboratory director failed to specify in writing the responsibilities and duties of personnel responsible for all phases of patient testing. Findings included: 1. Review of personnel records found no written job descriptions or delegation of duties for the technical consultant, laboratory director, clinical consultant or testing personnel. 2. Review of policies and procedures found no written job descriptions or delegation of duties for the technical consultant, laboratory director, clinical consultant or 8 testing personnel listed on the CMS report 209. 3. Interview of testing personnel conducted on June 25, 2018 at 3:57 PM confirmed that there were no written job descriptions or delegation of duties for all positions.
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 review of laboratory policies and procedures, quality control records, patient test records, and confirmed in interview with laboratory staff, the technical consultants failed to provide technical and scientific oversight. 1. The technical consultant failed to ensure that verification procedures used to verify the performance specifications for the Abbott iSTAT were adequate to determine accuracy , precision and other performance specifications. (see D 6040) 2. The technical consultant failed to ensure that the laboratory was enrolled in an HHS (Health and Human Services) approved proficiency testing program for Hematology. (see D6041) 4. The technical consultant failed to ensure that a quality control program had been established and maintained to ensure the accuracy and reliability of results obtained when using the Prothrombin Time/INR tested on the Abbott iSTAT . (See D6042) 5. The technical consultant failed to evaluate the competency of testing personnel at least semiannually in the first year of testing and annually and annually thereafter. (See D6053 and D6054)
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 a review of laboratory verification studies, quality control records, patient records, and confirmed in interview with laboratory staff, the Technical Consultant failed to ensure that verification procedures were performed for the Abbott iSTAT analyzer prior to testing patient specimens. (See D5421)
D6041	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(3) (b) The technical consultant is responsible for-- (b)(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services

	offered; This STANDARD is not met as evidenced by: Based on review of laboratory records and interview of facility personnel, the Technical Consultant failed to ensure the laboratory was enrolled in a proficiency testing program for Hematology. (See D 2000)
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 observations, review of quality control records, patient test records and interview of facility personnel found that the technical consultant failed to establish and maintain the quality control program for PT/INR and ACT tested on the Abbott i-STAT. (see D5441)
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 records, the CMS-209 Laboratory Personnel report, and confirmed in interview, the Technical Consultant failed to evaluate and document the performance of two of eight testing personnel at least semi-annually in the first year of testing ACT and PT/INR using the Abbott i-STAT. The findings included: 1. Based on review of laboratory records, laboratory had been testing patient specimens for PT/INR and ACT since November 2016. 2. Review of personnel records found no annual competency assessments for two of eight testing personnel. Testing person five had a hire date of August 2016. Testing person eight had a hire date of July 2016. There was no documentation of semi annual competency assessments performed between November 2016 and June 25, 2018. 3. Interview of testing person eight conducted on June 25, 2018 at 9:48 AM confirmed there were no semi annual competency assessments for testing persons five and eight.
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 records, the CMS-209 Laboratory Personnel report, and confirmed in interview, the Technical Consultant failed to evaluate and document the performance of two of eight testing personnel at least annually. The findings included: 1. Based on review of laboratory records, laboratory had been testing patient specimens for PT/INR and ACT since November 2016. 2. Review of personnel records found no annual competency assessments for two of eight testing personnel. Testing person five had a hire date of August 2016. Testing person eight had a hire date of July 2016. There was no documentation of annual competency assessments performed between November 2016 and June 25, 2018. 3. Interview of testing person eight conducted on June 25, 2018 at 9:48 AM confirmed there were no annual competency assessments for testing persons five and eight.
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 CMS-209 laboratory personnel report, and staff interview, the laboratory failed to have documentation of education and training to qualify one of eight testing personnel performing PT/INR and ACT testing using the Abbott i-STAT (see D6065 and D6066).
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: Review of laboratory records and interview of facility personnel found that one of eight testing personnel listed on the CMS Report 209 had no documentation of education available for review prior to testing patient specimens for PT/INR and ACT using the Abbott i-STAT. Findings included: 1. Review of personnel records found no documentation of education for testing person three (hire date March 2017) listed on the CMS Report 209. Education records were requested but not provided. 2. Interview of testing person eight conducted on June 25, 2018 at 9:48 AM confirmed that education records were not available for testing person three.

D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. This STANDARD is not met as evidenced by: Review of laboratory records and interview of facility personnel found that one of eight testing personnel listed on the CMS Report 209 had no documentation of training available for testing patient specimens for PT/INR and ACT using the Abbott i-STAT. Findings included: 1. Review of personnel records found no documentation of training for testing person three (hire date March 2017) listed on the CMS Report 209. Education records were requested but not provided. 2. Interview of testing person eight conducted on June 25, 2018 at 9:48 AM confirmed that training records were not available for testing person three.