Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0487813	06/11/2019
Name of Provider or Supplier	**Street Address, City, State**	
Wilbarger General Hospital Laboratory	920 Hillcrest Drive, Vernon, 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	As a result of the CLIA recertification inspection performed on June 11, 2019, the laboratory is not in compliance with the following Conditions of Participation required for certification in the CLIA program at 42 CFR: D5026 - 42 C.F.R. 493.1217 Condition: Immunohematology; D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director; D6063 - 42 C.F.R. 493.1412 Condition: Laboratories performing moderate complexity testing; testing personnel; D6076 - 42 C.F.R. 493.1441 Condition: Laboratories performing high complexity testing; laboratory director
D2005	ENROLLMENT CFR(s): 493.801(a)(4) Authorize the proficiency testing program to release to HHS all data required to-- (i) Determine the laboratory's compliance with this subpart; and (ii) Make PT results available to the public as required in section 353(f)(3)(F) of the Public Health Service Act. This STANDARD is not met as evidenced by: Based on review of the CMS 155D proficiency testing reports, review of the laboratory's College of American Pathologists proficiency testing records from 2018 and 2019 (4 of 4 events reviewed) and staff interview, the laboratory failed to ensure proficiency testing data was released to HHS. The findings were: 1. A review of the laboratory's CMS 155D proficiency testing reports revealed proficiency testing data was not being collected by CMS. 2. A review of the laboratory's College of American Pathologists proficiency testing records from 2018 (events 1, 2, and 3) and 2019 (event 1) revealed the proficiency testing agency was not sending data to HHS. In the proficiency testing instructions, the proficiency testing company wrote the following: "1. All laboratories subject to Clinical Laboratory Improvement Amendments (CLIA) regulations: If your laboratory is beginning or discontinuing testing on any CMS-regulated analyte, you must check your CMS Analyte Reporting Selections to ensure

	no changes are needed. You can maintain your laboratory's current reporting preferences by accessing the application via e-LAB Solutions Suite under Proficiency Testing/Quality Management." 3. An interview with the Respiratory Therapy Manager on 06/11/2019 at 12:47 hours revealed she was unaware that HHS was not receiving the proficiency testing data as required.
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: Review of proficiency testing records and interview of facility personnel, the laboratory failed to test proficiency samples the same number of times as it tests patient specimens for the assay 25-0H Vitamin D- on the first event of 2019 (3 events per calendar year) for 3 of 3 proficiency samples. Findings included: 1. Review of The American Proficiency Institute (API) proficiency testing records for the first event of 2019 found that the laboratory tested proficiency specimens IAS-01, IAS-02, and IAS-03 in duplicate on 4/29/2019. 2. Interview of the Laboratory Manager conducted on June 11, 2019 at 10:06 am in the laboratory confirmed that the laboratory tested 3 of 3 proficiency specimens two times each and that patient specimens were not tested two times each.
D3025	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(d) Investigation of transfusion reactions. The facility must have procedures for preventing transfusion reactions and when necessary, promptly identify, investigate, and report blood and blood product transfusion reactions to the laboratory and, as appropriate, to Federal and State authorities. This STANDARD is not met as evidenced by: Based on review of hospital policies and confirmed in interview, the facility failed to ensure end user nursing personnel were adequately trained on detecting and alerting on possible transfusion reactions to ensure prompt identification of transfusion reactions for all hospital patients receiving blood or blood components. The findings included: 1. Review of facility policy "Blood and Blood Component Administration" (PolicySTAT ID: 5481135) on page 2 stated, "13. Suspected adverse blood transfusion reactions will be communicated to the ordering physician, laboratory /laboratory director, and nursing supervisor, and documented in the patient's medical record." 2. Further review of the policy on page 8 provided an example of a Febrile Non-Hemolytic Transfusion Reaction (FNHTR). The policy defined FNHTR as, "Within 1-2 hours and up to 4 hours: AND EITHER (Fever greater than or equal to 38 degrees Celsius/100.4 Fahrenheit oral and a change of at least 1 degree Celsius/1.8

	degrees Fahrenheit from pre-transfusion value OR Chills/rigors are present." 3. Random review of duplicate transfusion forms stored in the laboratory found the following 1 of 30 patients from May 2018 to June 2019 with vital signs documentation. The vital signs included temperature documenation: Patient Identification: Account #707281 (Transfused: 12-02-2018) Time Temp Stats 1750 98.4 (baseline) 15 minute check @ 1805 98.6 30 minute check @ 1820 98.6 First Hour @ 1850 98.1 Second Hour @ 1950 101.1 (increase of 2.7 degrees Fahrenheit from baseline) Third Hour @ 2050 101.8 (increase of 3.4 degrees Fahrenheit from baseline) Blood Discontinued @ 2105 101.3 (increase of 2.5 degrees Fahrenheit from baseline) 4. Review of patient chart records found that in the patient's progress notes at 19:50 it stated, "Second Hour Check: No changes from previous assessment, no signs or symptoms of transfusion reaction. Lung sounds clear bilaterally." -Note: Patient's Progress Notes and the duplicate form that is sent to the lab do not match. The duplicate form indicated that the patient had a fever of greater than 100.4 with a 2.7 degree Fahrenheit increase in temperature from the baseline. The increase in patient's temperature was not documented in the Progress Notes until 21:05 (1 hour and 15 minutes later). a. There was no documentation that the facility followed its policy to notify the ordering physician, laboratory director/laboratory, and the nursing supervisor. 5. Review of the patient's progress notes at 20:50 stated, "Third Hour Check: No changes from previous assessment, no signs or symptoms of transfusion reaction. Lung sounds clear bilaterally." -Note: Patient's Progress Notes and the duplicate form that is sent to the lab do not match. The duplicate form indicated that the patient had a fever of greater than 100.4 with a 3.4 degree Fahrenheit increase in temperature from the baseline. The increase in patient's temperature was not documented in the Progress Notes until 21:05 (15 minutes later). a. There was no documentation that the laboratory followed its policy to notify the ordering physician, laboratory director/laboratory and the nursing supervisor. 6. Review of the patient's progress notes at 21:05 stated, "Febrile Reaction > Degrees Rise in Temp: 101.1 2d hour at right temple, 101.8 3d hour at right temple, 101.3 at transfusion end at right temple, 100.8 at left forehead and 100.6 at right forehead. There was no documentation that the facility followed its own policy to contact the ordering physician, laboratory/laboratory director, and the nursing supervisor. 7. Interview with the Infection Preventionist (scribe) on June 11, 2019 confirmed the findings. After her review of the records she agreed that the transfusion should have been stopped and further instructions obtained.
D5026	IMMUNOHEMATOLOGY CFR(s): 493.1217 If the laboratory provides services in the specialty of Immunohematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1271, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on surveyor's review of Immunohematology records, patient records, and interviews, the laboratory failed to meet applicable requirements in the specialty of Immunohematology (refer to D5559).
D5207	COMMUNICATIONS CFR(s): 493.1234 The laboratory must have a system in place to identify and document problems that

occur as a result of a breakdown in communication between the laboratory and an authorized person who orders or receives test results.

This STANDARD is not met as evidenced by:
Based on review of hospital policies, review of patient transfusion records, and confirmed in interview, the laboratory failed to implement a system to identify and document problems that occurred when a breakdown in communication occurred between the provider and the laboratory. The findings included: 1. Review of facility policy "Blood and Blood Component Administration" (PolicySTAT ID: 5481135) on page 2 stated, "13. Suspected adverse blood transfusion reactions will be communicated to the ordering physician, laboratory/laboratory director, and nursing supervisor, and documented in the patient's medical record." 2. Further review of the policy on page 8 provided an example of a Transfusion Associated Circulatory Overload (TACO). The policy defined a TACO as, "Onset or exacerbation within 1-2 hours and up to 6 hours: -Dyspnea -Orthopnea -Hypertension (increase in 30 mm hg) -Increased BNP -Radiographic evidence of pulmonary edema -Evidence of left heart failure -Increased CVP -Gallop -JVD -New ST-segment and T-wave changes in EKG -Elevated serum Troponin -Increased BP characterized by widening of pulse pressure -Radiographs show a widened cardio thoracic ratio" 3. Review of transfusion vital signs ("Record of Patient's Response") found on duplicate forms located in the laboratory revealed the following 1 of 30 patients with documentation as follows: Patient ID: Last four digits of Account #: 9952 (Patient Date of Birth: 02-11-1945) According to the "Record of Patient's Response" for the 2nd unit of blood (Donor Unit #W0910 19 108821), the following vital signs were documented by the RN (registered nurse): Time Temp Blood Pressure Oxygen Saturation Prior to transfusion 14:05 97.7 101/62 93% 15 minute check 15:00 97.7 104/68 94% 30 minute check 15: 15 97.8 127/80 100% First hour 15:45 98.1 105/75 99% Second hour 16:45 97.7 148 /100 61% Blood discontinued 16:50 97.9 152/100 60% "Was there a reaction to blood? Yes" and "If so, was blood reaction form completed and lab notified? Yes." 4. The area on the form where nursing staff are to document which laboratory technologist was notified was left blank. 5. Review of the patient chart records in the "Discharge Summary" stated, " ...ED Physician 1 (alias) was notified of the critical status of the patient. He came up and took over care and intubated patient successfully. Patient was started on albumin and epinephrine drip to help stabilize her blood pressure. Hospital 2 (alias) was called and accepted transfer. Air Evacuation Service 1 (alias) will transport patient to Hospital 2 (alias)." 6. Review of patient post-transfusion laboratory test results revealed the following: Troponin = 0.27 ng/mL (hc) (Reference Range = 0.0 - 0.02 ng/mL) Date and Time Resulted: 02-28-2019 @ 1726 BNP = 1440 pg/mL (Reference Range = 0 - 100 pg/mL) Date and Time Resulted: 02-28-2019 @ 1726 Urinalysis Blood = 2+ (Reference Range = Negative) 7. Interview with testing personnel two (as listed on CMS-Form 209) on June 11, 2019 at 14:45 hours in the laboratory confirmed the findings. He revealed that he presented to the floor where the patient was and that ED Physician 1 (alias) told him not to work up as a transfusion reaction because the patient's reaction was due to giving the blood too fast and not a transfusion reaction. Testing Personnel two went on to say that based on the information he was given a transfusion reaction investigation was not performed. 8. Interview with the Laboratory Director, Chief Executive Officer, Nurse Practitioner 1, Laboratory Manager, Respiratory Therapy Manager, and scribes on June 11, 2019 at 17:20 hours confirmed that as of the exit conference, the facility did not know the patient's outcome. Key: mm hg - millimeters mercury BNP - Brain Natriuretic Peptide CVP - Central Venous Pressure JVD - Jugular Vein Distention EKG - Electrocardiogram BP - Blood Pressure ED - Emergency Department ng/ml -

	nanograms per milliliter hc - high critical pg/ml - picograms per milliliter CMS - Centers for Medicare and Medicaid Services
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of Instrumentation Laboratories (IL) manufacturer instructions, laboratory procedures, new instrument verification studies, and interview with facility personnel, the laboratory failed to follow instructions for establishment and verification of the patient normal range for Protime assays. The findings included: 1. Based on review of the IL manufacturer instructions (PN 774413A), under CHANGING LOT NUMBER OF REAGENT, the instructions state the following: "When changing to a new lot number of reagent or a new reagent, it is important to establish a new normal reference interval, to establish new assay control ranges and to establish a heparin therapeutic range on APTT reagents." And; "Procedure 1. Perform 'Normal Reference Interval' procedure for PT and APTT using the new lot numbers of reagents." Under NORMAL REFERENCE INTERVAL, page 37, the instructions state: "Reference Interval should be established whenever there is a change in: *Instrument and/or methodology *Lot number of reagent *Sample collection procedures *At least once a year" Under Specimen Collection and Preparation, the document states: "Test 120 donors for a full reference interval study. Ideally specimens will be analyzed over a number of days, resulting in values that represent average run-to-run variation. You may use a 20 donor study under specific conditions. Refer to NCCLS C28-A for full details. The main condition are as follows: *You may transfer the reference interval from another lab within the same geographical region and for the same demographical population of test subjects. *The original site must have done a full reference study. *The original site must have used the identical type of analytic system (method, instrument and reagents) as the secondary site; or one that is acceptably comparable as described in NCCLS EP9-T. *Your 20 donors must fairly represent your population and the population of the original study. *This includes your own lab; if you did a 120 sample study the first time, subsequent studies may use 20 samples." Under Expected Values, the document states: "The original laboratory's reported 95 percent reference limits may be considered valued for use in the

	secondary lab if no more than 2 of the 20 tested subject's values fall outside those original reported limits and the pre-testing criteria were met." 2. Based on review of the laboratory's procedure "Protime (PT) and INR", last revised on 8/23/2016, the procedure does not include step-by-step instructions for verifying a previously established Protime patient normal reference interval or how to establish the normal reference interval if a full establishment has not been performed. 3. Based on review of the Instrument Performance Verification checklist for the new IL coagulation analyzer installed in October of 2018, the checklist included "Verification of Reference Interval". This checklist was signed by an IL representative on 10/11/2018. 4. Based on review of records from November 2018, the laboratory performed a new reference range establishment with 22 samples; the laboratory did not perform a reference range verification of a previously established patient normal range. The geometric mean of the normal patient range (MNPT) was calculated as 12.26 seconds. Based on surveyor observations, the MNPT in use on the coagulation analyzer was 11.9 seconds. 5. In an interview at 14:00 hours on 6/11/2019, the Laboratory Manager confirmed: *the laboratory could not find a reference range establishment study as described by the manufacturer instructions *the laboratory established MNPT from October through November 2018 was not in use and that the MNPT had been calculated from data from a previous instrument *the laboratory had changed reference ranges with each lot of reagent for Protime with studies of 20 to 25 samples and had not verified a full reference range establishment study.
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: Based on review of manufacturer's instructions, review of quality control records, and confirmed in interview of facility personnel, the laboratory failed to follow the manufacturer's instructions for quality control performance for Pouch-MicroAero sachets. The findings were: 1. Review of the manufacturer's instructions for Pouch-MicroAero sachets (Product Information Sheet 20-05 09/1720,000) it stated, "Quality Control: Quality Control testing should be performed periodically using Campylobacter jejuni ATCC 33291 growth." 2. Review of the laboratory's quality control records from January 2018 to March 2019 revealed no documentation that the laboratory was performing periodic quality control checks on the microaerophilic gas generating sachets. 3. An interview with testing personnel four (as listed on Form CMS-209) on June 11, 2019 in the Microbiology Department confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Services
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, Abbott i-STAT systems manual and interview facility personnel found that the laboratory failed to ensure that the room where the Abbott i-STAT analyzer was used to test patient specimens met the manufacturers requirements for relative humidity and barometric pressure for 92 of 92 days used for testing. The findings included: 1. Observations made during the inspection found no means to measure the humidity and barometric pressure in the room where the I STAT was used for patient testing. 2. Review of laboratory records found no documentation of humidity and barometric pressure for the room where the I STAT was used for patient testing. 3. Review of the Abbott i-STAT systems manual found on page 2 2 under the heading specifications: "Operating Temperature 16 to 30C (61 to 86F), relative humidity: 90% (maximum) noncondensing and barometric pressure 300 to 850 mm/Hg." 4. Interview of the respiratory therapy department director conducted on June 11, 2019 at 11:05 AM confirmed that the laboratory did not measure and record the humidity and barometric pressure of the room where the I STAT was used for patient testing. She states that "it was her understanding it was not required as per the manufacturer."
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 records for the Abbott I STAT, manufacturers specifications, patient test records and interview of facility personnel found that the laboratory failed to verify the analyzer met the manufacturers specifications for accuracy, precision, reportable range, and that reference intervals were appropriate for the laboratory's patient population for blood gases and lactic acid using the CG 4 cartridge. Findings included: 1. Review of the verification study for the CG 4 cartridges using the Abbott i-STAT serial number 404911 (completed on March 27, 2019) provided by the respiratory therapy department found a Total Imprecision study for levels 1 and 3 along with a calibration verification procedure for lactic acid, PCO2, pH and PO2. There was no documentation available for review for the verification of reference ranges, or for what specimen type. There was no documentation that the verification study had been reviewed by facility personnel. Further review of the instrument printouts found that the lactic acid values do not correlate with documented values for lactic acid on the Total Imprecision for levels 1 and 3. 2. Review of the Abbott i-STAT System Manual found reference ranges as follows: Lactic Acid: 0.362 1.25 mmol/L (arterial) and 0.90 to 1.70 mmol/L (venous) PCO2: 35 to 45 mm/Hg (arterial) and 41 to 51mm/Hg (venous) pH: 7.35 to 7.45 (arterial) and is 7.31 to 7.41 (venous) PO2: 80 to 105 mm/Hg 3. Review of patient test records for April and May 2019

	found that the laboratory tested 143 patient specimens using the CG4 cartridge without verifying the reference ranges met the manufacturers specifications. 4. Interview of the respiratory therapy department director conducted on June 11, 2019 at 11:25 AM confirmed that the laboratory did not verify the reference ranges in did not evaluate data to determine acceptability. She stated that the total imprecision studies ports for levels one and three and the calibration verification was all the documentation she had available. She further confirmed that she had no idea where the values for the lactic acids came from and had not noticed that they were not the same as on the printouts.
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: Review of policies and procedures and interview facility personnel found that the quality control procedure available to testing personnel for the performance and assessment of quality control procedures for the Abbott i-STAT used to test patient specimens for pH, PO2, PCO2 and lactic acid failed to define a means of monitoring over time for the accuracy and precision of test performance. The findings included: 1. Review of the policy and procedure manual found no instruction to testing personnel, the procedures necessary to monitor the performance of the quality control material over time using a Levy Jennings graphs or some other means. 2. Review of quality control records found that the laboratory printed instrument reports and taped them to a piece of paper and placed in the notebook for retention. 3. Interview of testing personnel conducted on June 11, 2019 at 1:14 PM confirmed that the laboratory did not use a Levy Jennings graphs or some other means to monitor over time the accuracy and precision of test performance.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on observations, review of policies and procedures, review of the manufacturer's operators guide, quality control records and interview of facility personnel, the laboratory failed to define the number and frequency of quality control materials to be tested in their own Individualized Quality control Plan (IQCP) for ABG's and lactic acid tested on the Abbott i STAT using the CG 4 cartridge. Findings included: 1. Observations made during the tour of the laboratory found iSTAT analyzer serial number. 404911 available for use in testing patient specimens using the CG 4 cartridges. 2. Review of the laboratory's policy/ procedure titled Individualized Quality Control Plan For I-STAT One System (approved March 29, 2019) found: a. The laboratory failed to define the number and frequency of quality control materials tested in the quality control plan. on page 8 under the heading Liquid Controls: " internal liquid controls are performed at intervals recommended by the manufacturer." b. The laboratory failed to to assess the historical data to define the frequency and impact for possible sources of error identified in the risk assessment. c. The laboratory failed to include a quality assessment procedure in their own IQCP. 3. Review of the Abbott i-STAT systems manual found on page 14 -1Review of quality control records between March 29, 2019 and June 11, 2019 found that the laboratory did not test at least one level of liquid controls at least once every eight hours . Documented quality control procedures for the CG 4 cartridge tested on the I STAT analyzer Serial number. 404911 were as follows: a. April 30, 2019: three levels of quality control materials were tested using CG 4 cartridge lot 210D190080243 b. May 13, 2019: three levels of quality control materials were tested using CG 4 cartridge lot 210D190851243 c. May 22, 2019: three levels of quality control materials were tested using CG 4 cartridge lot 210D190891243 d. May 30, 2019: three levels of quality control materials were tested using CG 4 cartridge lot 210D190891243 4. Review of patient test records found that 143 patients were tested using three lots of CG4 cartridges. 23 patient samples were tested using CG 4 cartridge lot 210D190851243 without quality controls being tested prior to testing patient specimens. 5. Interview of the respiratory therapy department director confirmed that the laboratory had no additional documentation of quality control procedures, showing quality control procedures were performed for each new lot, shipment, or every 30 days. She confirmed that the laboratory did not perform quality control testing with each new lot only once every 30 days.
D5537	ROUTINE CHEMISTRY CFR(s): 493.1267(b)(d) For blood gas analyses, the laboratory must perform the following: (b) Test one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values on each day of testing. (d) Document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on observations, review of policies and procedures, review of the manufacturer's operators guide, quality control records and interview of facility personnel, the laboratory failed to test quality control material at least one level every eight hours, or define the number and frequency quality control materials to be tested in their own Individualized Quality control Plan (IQCP) used to decrease the frequency for ABG's tested on the Abbott i STAT using the CG 4 cartridge. Findings included: 1. Observations made during the tour of the laboratory found iSTAT analyzer serial number. 404911 available for use in testing patient specimens using

	the CG 4 cartridges. 2. Review of the laboratory's policy/ procedure titled Individualized Quality Control Plan For I-STAT One System (approved March 29, 2019) found: a. The laboratory failed to define the number and frequency of quality control materials tested in the quality control plan. on page 8 under the heading Liquid Controls: " internal liquid controls are performed at intervals recommended by the manufacturer." b. The laboratory failed to to assess the historical data to define the frequency and impact for possible sources of error identified in the risk assessment. c. The laboratory failed to include a quality assessment procedure in their own IQCP. 3. Review of the Abbott i-STAT systems manual found on page 14 -1Review of quality control records between March 29, 2019 and June 11, 2019 found that the laboratory did not test at least one level of liquid controls at least once every eight hours . Documented quality control procedures for the CG 4 cartridge tested on the I STAT analyzer Serial number. 404911 were as follows: a. April 30, 2019: three levels of quality control materials were tested using CG 4 cartridge lot 210D190080243 b. May 13, 2019: three levels of quality control materials were tested using CG 4 cartridge lot 210D190851243 c. May 22, 2019: three levels of quality control materials were tested using CG 4 cartridge lot 210D190891243 d. May 30, 2019: three levels of quality control materials were tested using CG 4 cartridge lot 210D190891243 4. Review of patient test records found that 143 patients were tested using three lots of CG4 cartridges. 23 patient samples were tested using CG 4 cartridge lot 210D190851243 without quality controls being tested prior to testing patient specimens. 5. Interview of the respiratory therapy department director conducted on June 11, 2019 at 1:21 PM confirmed that the laboratory had no additional documentation of quality control procedures being tested at least one level every eight hours, or showing quality control procedures were performed for each new lot, shipment, or every 30 days. She confirmed that the laboratory did not perform quality control testing with each new lot, only once every 30 days.
D5559	IMMUNOHEMATOLOGY CFR(s): 493.1271(e)(f) (e) Investigation of transfusion reactions. (e)(1) According to its established procedures, the laboratory that performs compatibility testing, or issues blood or blood products, must promptly investigate all transfusion reactions occurring in facilities for which it has investigational responsibility and make recommendations to the medical staff regarding improvements in transfusion procedures. (e)(2) The laboratory must document, as applicable, that all necessary remedial actions are taken to prevent recurrences of transfusion reactions and that all policies and procedures are reviewed to assure they are adequate to ensure the safety of individuals being transfused. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of the facility's transfusion reaction policies, patient records, laboratory transfusion reaction investigation records and confirmed in interview, the laboratory failed to perform its responsibility to document a blood bank transfusion reaction investigation for random review of 2 of 30 patients from July 2018 to March 2019. The findings included: 1. Review of the laboratory's policy titled, "Transfusion Reaction Investigation" (Procedure B30-0903.10) approved by the laboratory director stated in the section titled "Principle: 1. Transfusion reaction is defined as any unexpected or untoward sign or symptom that occurs during or shortly after the transfusion of blood or one of it's [sic] components and should be considered as

caused by the donor unit until proven otherwise. Catastrophic clinical events may occur in an acute hemolytic transfusion reaction, therefore if the symptoms or findings suggest a hemolytic transfusion reaction the transfusion must discontinued immediately. 2. Immediate investigation as to the cause of any suspected transfusions reaction is required so the recipient can be appropriately treated. 3. All patient symptoms, clerical checks, pre and post reaction testing, investigation review and required reports including an incident report will be thoroughly and completely documented. This information will be placed in a packet and forwarded to the Laboratory Manager and in turn to the Laboratory Medical Director who will determine if the Blood Supplier and the FDA as well as other regulatory agencies requires notification. 4. It is absolutely imperative that ALL documentation remain together and get forwarded through the review process until it becomes part of the recipient's Medical Record." Review of the policy under, "Procedure: (Initiation Instructions) states, "1. If nursing services reports a suspected transfusion reaction, have them initiate the following steps. 2. Discontinue the transfusion immediately but keep the intravenous line open. 3. Check the identification on the donor bag label and the patient documents against the patient's Blood Bank ID Band and Hospital ID Band. 4. Notify the physician. 5. Complete and sign the Suspected Transfusion Reaction Form obtained from the laboratory. 6. Submit an order for a Transfusion Reaction Workup in CPSI. 7. Submit a post-reaction urine specimen to the laboratory. 8. Submit the donor unit bag and infusion set to the laboratory." a. The policy did not provide criteria for "unexpected" or "untoward" signs or symptoms that could occur during or after a transfusion. This was confirmed in an interview with Testing Personnel three (as listed on Form CMS-209) on June 11, 2019 at 10:30 hours in the laboratory. She stated, "Nursing are the ones who would call the transfusion reaction." b. The policy listed a reference that the laboratory does not have. The facility has the "Technical Manual of American Association of Blood Banks 18th Edition," and the policy refers to the 16th Edition. However, according to the 18th edition, it states: "Many common clinical signs and symptoms are associated with more than one type of adverse reaction. Early recognition, prompt cessation of the transfusion, and further evaluation are key to a successful outcome. The signs and symptoms that may be indicators of a transfusion reaction include the following: -Fever, generally defined as >/= 1 degree Celsius rise in temperature above 37 degrees Celsius [the most common sign of an acute HTR (AHTR)] -Chills with or without rigors -Respiratory distress, including wheezing, coughing, and dyspnea -Hyper-or hypotension -Abdominal, chest, flank, or back pain, -Pain at the infusion site -Skin manifestations, including urticaria, rash, flushing, pruritus, and localized edema, -Jaundice or hemoglobinuria -Nausea/vomiting -Abnormal bleeding -Oliguria/anuria" 2. Review of blood transfusion records from July 2018 to March 2019 found the following 2 of 30 randomly reviewed cases when a patient exhibited signs and symptoms of a transfusion reaction or nursing documented a reaction to blood transfusion, but a transfusion reaction investigative workup was not performed. a. Patient Account Number 709952 (Date of birth 02-11-1945) was identified by nursing staff as having a suspected transfusion reaction after receiving 2 units of LRBCs on February 28, 2019. 2nd Unit Transfused: Unit # W0910 19108821 Blood discontinued: 16:50 hours Final Temp: 97.9 Final BP: 152/100 (baseline: 101/62) Final Pulse: 140 (baseline: 107) Blood Warmer: Not Applicable RN: initials RG O2 Saturation: 60% (baseline: 93%) Amount Given: Was there a reaction to blood? Yes If so, was blood reaction form completed and lab notified? Yes Tech notified: this area was left blank There was no documentation that the laboratory performed a transfusion reaction workup. This was confirmed in interview with the Laboratory Manager on June 11, 2019 at 13:15 hours in the laboratory. She confirmed that she reviewed blood bank records and that 2009 was the last time the laboratory had performed a transfusion reaction workup. b.

	Patient Identification: Account #707281 (Transfused: 12-02-2018) Time Temp Stats 1750 98.4 (baseline) 15 minute check @ 1805 98.6 30 minute check @ 1820 98.6 First Hour @ 1850 98.1 Second Hour @ 1950 101.1 (increase of 2.7 degrees Fahrenheit from baseline) Third Hour @ 2050 101.8 (increase of 3.4 degrees Fahrenheit from baseline) Blood Discontinued @ 2105 101.3 (increase of 2.5 degrees Fahrenheit from baseline) Review of the patient's progress notes at 21:05 stated, "Febrile Reaction > Degrees Rise in Temp: 101.1 2d hour at right temple, 101.8 3d hour at right temple, 101.3 at transfusion end at right temple, 100.8 at left forehead and 100.6 at right forehead. There was no documentation that the laboratory performed a transfusion reaction workup. This was confirmed in interview with the Laboratory Manager on June 11, 2019 at 13:15 hours in the laboratory. She confirmed that she reviewed blood bank records and that 2009 was the last time the laboratory had performed a transfusion reaction workup. 4. This was confirmed in an interview with Testing Personnel three (as listed on Form CMS-209) on June 11, 2019 at 10:30 hours in the laboratory. She stated, "Nursing are the ones who would call the transfusion reaction." Key: FDA - Food and Drum Administration CMS - Centers for Medicare and Medicaid Services
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: The laboratory failed to have a quality assessment plan to monitor, identify and correct problems within the analytic systems. The laboratory failed to identify that verification studies for the CG 4 panel tested on the Abbott i-STAT were incomplete and had not been evaluated against the manufacturers specifications for acceptability. (See D5421) the laboratory failed to identify that humidity and barometric pressure was measured and recorded for the room where the Abbott i-STAT was used for patient testing. (See D5413)
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of patient records, blood utilization records, facility clinical minutes, laboratory policies, and confirmed in interview with facility personnel, the laboratory's established policies and procedures failed to monitor, assess, and when indicated, correct problems identified in transfusion medicine. The findings included: NOTE: For problems identified in transfusion medicine, refer to D5559. The laboratory's quality assurance mechanism failed to identify and correct problems

identified, such as: A. Underreporting of transfusion reactions by the facility B. Policies/procedures failed to include the definition of vital signs to be obtained prior, during, and after a transfusion C. Policies/procedures failed to include transfusion criteria for LRBCs prior to transfusion D. Policies/procedures failed to include review of patient records to assist the facility in recognizing potential transfusion reactions A. Underreporting of transfusion reactions by the facility 1. Review of the facility's "Blood Products Utilization 2018" revealed the following statistics: Blood Product Amount Transfused 2018 Crossmatched LRBCs 219 Platelets 5 FFP 7 Emergency Released 3 Major Transfusion Reactions 0 Minor Transfusion Reactions 0 Total Products Given in 2018: 234 2. Review of laboratory transfusion records revealed that the laboratory had not worked up a potential transfusion reaction since 2009. This was confirmed in interview with the Laboratory Manager on June 11, 2019 at 13:15 hours in the laboratory. She stated that she had reviewed records and confirmed that 2009 was the last time the laboratory had performed a transfusion reaction workup. 3. Random review of "General Hospital Minutes" from May 2018 to April 2019 included blood utilization review. Blood utilization metrics were included in the minutes: May 6, 2019 " ...[Laboratory Manager] reported that blood usage for this month had increased. She said overall transfused to cross matched percentage was 73%, and the ER transfused to cross matched percentage was 75%. No patient received more than 4 units of LRBC or blood products, and there was not transfusion reaction this month ..." March 5, 2019 Note: This meeting was 5 days after nursing staff identified a transfusion reaction for Patient Account Number 709952 on February 28, 2019 (refer to D5559). "[Laboratory Manager] included in her reports but was not present for this meeting. [Physician 2] gave a brief overview, stating blood usage had decreased for the month of February. He stated there should be 2 sets of blood cultures performed each time, as contaminates make this hard to track. ... discussed the transfused to cross matched percentages, and stated they would like to know more about the statistics." August 13, 218 "..Blood usage for the month increased." June 5, 2018 " ...Blood usage for May had increased." May 7, 2018 " ... Blood usage for April increased." 4. The facility recognized and documented increases in blood utilization for the records reviewed. 5. Interview with the Laboratory Manager on June 11, 2019 at 13:15 hours in the laboratory revealed that she had reviewed laboratory records and confirmed that 2009 was the last time the laboratory had performed a transfusion reaction workup. B. Policies/procedures failed to include the definition of vital signs to be obtained prior, during, and after a transfusion. 1. Review of the laboratory's policy titled, "Blood & Blood Product Administration" (effective date, 04/08/2009) with an approval date by the laboratory director on November 6, 2017 under "Patient Monitoring" it stated: "11 Patient Monitoring: 11.3 Monitor the recipient for the following complications: 11.3.1 Pyrexial (febrile) reactions: 11.3.1.1 Rise in temperature 11.3.1.2 Chills 11.3.1.3 Nausea 11.3.1.4 Vomiting 11.3.2 Allergic Reactions: (1-2% of patients) 11.3.2.1 Hives 11.3.2.2 Rash 11.3.2.3 Itching 11.3.3 Bacterial Reaction 11.3.3.1 Fever 11.3.3.2 Chills 11.3.3.3 Pain 11.3.3.4 Hypotension 11.3.3.5 Shock 11.3.4 Incompatibility Reaction: (1 per 15,000) 11.3.4.1 Severe Aching Pain (flank, shoulder, back, hamstring) 11.3.4.2 Burning at the IV site 11.3.4.3 Chest Pain/Tightness 11.3.4.4 Anxiety 11.3.4.5 Nausea & Vomiting 11.3.4.6 Hemoglobinuria & Oliguria 11.3.4.7 Increase in Temperature & Respiration 11.3.4.8 Headache 11.3.4.9 Chills 2. The policy failed to include the definitions of temperature or a rise in temperature. 3. The laboratory listed the "Technical Manual of American Association of Blood Banks 16th Edition" as one the references at the end of the policy. The facility did not have the 16th Edition available for review. However, it did have a more current edition, the 18th edition, and it stated: "Identification of a Transfusion Reaction: As with many necessary medical therapies, adverse effects cannot always be accurately predicted or

avoided. The transfusing physician should be aware of such risks when discussing the need for transfusion with a patient. Informed consent for transfusion may include a discussion of the risks of infectious disease and serious noninfectious complications, such as TRALI, and HTRs. Furthermore, medical staff administering blood components should be well aware of the signs and symptoms of possible reactions. These staff should be prepared to mitigate the current episode and prevent future similar reactions when possible. Many common clinical signs and symptoms are associated with more than one type of adverse reaction. Early recognition, prompt cessation of the transfusion, and further evaluation are key to a successful outcome. The signs and symptoms that may be indicators of a transfusion reaction include the following: -Fever, generally defined as a 1 degree Celsius rise in temperature above 37 Celsius [the most common sign of an acute HTR (AHTR)]. -Chills with or without rigors. -Respiratory distress, including wheezing, coughing, and dyspnea. -Hyper- or hypotension. -Abdominal, chest, flank, or back pain. -Pain at the infusion site. -Skin manifestations, including urticaria, rash, flushing, pruritus, and localized edema. -Jaundice or hemoglobinuria. -Nausea/vomiting. -Abnormal bleeding. - Oliguria /anuria." 4. For problems identified in transfusion medicine, refer to D5559. 5. This was confirmed in an interview with Testing Personnel three (as listed on Form CMS-209) on June 11, 2019 at 10:30 hours in the laboratory. She stated, "Nursing are the ones who would call the transfusion reaction." C. The laboratory's quality assurance program failed to ensure that laboratory policies and procedures included transfusion criteria for LRBCs (leuko-reduced red blood cells). 1. Review of the facility's "Clinical Review Minutes" from May 2018 to April 2019 revealed the following was documented in August 2018, "The committee questioned why three patients who were listed as having transfusions were also listed as having a pre-transfusion Hgb number greater than 8.0 prior to the transfusion. [Physician 2] questioned if the numbers were correct ...." 2. Review of the laboratory' policy titled, "Blood & Blood Product Administration" (effective date 04/08/2009) approved by the laboratory director on November 6, 2017 stated, "1.3 An inhouse hemoglobin and hematocrit is preferred by not required by the laboratory to verify the patient's need for donor blood prior to administration." The policy failed to include H & H criteria (H & H values). 3. Email correspondence on June 13, 2019 revealed the facility did not have a policy available for review that was approved by the laboratory director for transfusion criteria for LRBCs. D. The laboratory's quality assurance program failed to ensure that laboratory policies and procedures included review of patient records (vital signs) that would assist the facility in identifying potential transfusion reactions. 1. Review of the laboratory' policy titled, "Blood & Blood Product Administration" (effective date 04 /08/2009) approved by the laboratory director on November 6, 2017 under "Quality Assurance Review" it stated: "14.4 The following criteria will be monitored as part of the Transfusion Review Process: 14.4.1 Signout Log Documentation 14.4.2 Unit Tag /Requisition Documentation 14.4.3 Document Transfusion Start & Stop Times 14.4.4 Unit Tag/Requisition Signatures 14.4.5 Patient Involvement in Identification 14.4.6 Use Patient & Blood Bank ID Bank in ID Process 14.4.7 Check ID Bands Against Unit Label & Requisition 14.4.8 Resolve All Discrepancies Before Hanging Blood 14.4.9 Insure the Patient Has Hospital & Blood Band ID Band 2. Review of blood bank records found that the laboratory receives yellow duplicated copies of the Blood Request Forms. Nursing staff document patient vitals on the form. The laboratory failed to include as part of its quality assurance review a mechanism to review the patient vitals along with patient records to assist the facility in recognizing and identifying potential transfusion reactions. 3. For problems identified in transfusion medicine, refer to D5559. 4. This was confirmed in an interview with Testing Personnel three (as listed on Form CMS-209) on June 11, 2019 at 10:30 hours in the laboratory. She stated, "Nursing are the ones who would call the transfusion reaction."

	Key: HTR - Hemolytic Transfusion Reaction FFP - fresh frozen plasma H & H - hemoglobin and hematocrit TRALI - transfuion related acute lung injury CMS - Centers for Medicare and Medicaid Services
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on a review of the manufacturer instructions for use, review of patient test records, and interview of facility personnel the laboratory failed to ensure that the appropriate reference ranges (normal values) were listed on the patient report for the analytes pH, PO2, PCO2 and lactic acid for 10 of 10 patient reports reviewed. Two of four analytes had reference ranges listed differently than in the Abbott i-STAT system manual. The findings included: 1. 2. Review of the Abbott i-STAT System Manual found reference ranges as follows: Lactic Acid: 0.362 1.25 mmol/L (arterial) and 0.90 to 1.70 mmol/L (venous) PCO2: 35 to 45 mm/Hg (arterial) and 41 to 51mm/Hg (venous) pH: 7.35 to 7.45 (arterial) and is 7.31 to 7.41 (venous) PO2: 80 to 105 mm /Hg 2. Review of 10 random patient reports indicated that the reference ranges provided on the patient reports for each of the four analytes were as follows: Lactic Acid: 0.50 to 2.0 mmol/L PCO2: 35 to 45 mm/Hg pH: 7.35 to 7.45 PO2: 80 to 100 mm/Hg The reference ranges on the final reports differed from the manufacturers ranges for two of four analytes lactic acid and PO2. 3. Interview of the respiratory therapy department director conducted on December 11, 2019 at 11:25 AM found that the reference ranges were not updated in the computer system with the recent change in analyzers used for broadcast testing. She went on to say that the reference ranges on the patient real for were from the OPTi CCA (the previous analyzer). She went on to stay that she didn't even think about updating the reference ranges in the computer.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by:
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: Review of personnel records, proficiency testing records, quality control records,

	patient test records and interview of facility personnel the laboratory director failed to provide overall management and direction. The laboratory director failed to ensure that the room where the Abbott i-STAT test system was used for testing patient specimens met the manufacturers specifications for humidity and barometric pressure. (See D5413) The laboratory director failed to ensure that verification studies had been completed and were assessed for acceptability for the Abbott i-STAT using the CG4 cartridges for blood gas analysis. (See D5421) The laboratory director failed to establish and maintain the quality control program for blood gas analysis. (See D5441, 5445, and D5539)
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: Review of verification studies, manufacturers specifications and interview of facility personnel found that the laboratory director failed to ensure the verification studies for the CG 4 panel tested on the Abbott i-STAT were complete and acceptable. (See D5421)
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 CG4 cartridges 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, the 5445, D5539)
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 seven of seven testing personnel performing blood gas testing using the Abbott i-STAT had the appropriate education and training for performing non waived procedures. (see D 6065 and D6066)
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:
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 of the CMS-209 Laboratory Personnel report, review of personnel files and confirmed in interview, the Technical Consultant failed to evaluate and document the semiannual competency assessment for five of seven moderate complexity testing personnel in 2018. The findings included: 1. Review of the CMS at 209 laboratory personnel report found seven testing personnel listed as performing moderate complexity testing in the blood gas laboratory. 2. Review of personnel records found no annual competency assessment performed in 2018 for two of seven testing personnel. Moderate complexity testing person one had a hire date of June 2018 with no semiannual competency assessmentsthe first year of testing. Moderate complexity testing person two had a hire date of September 17, 2018 with no semiannual competency assessment for the last half of first year of testing. Moderate complexity testing person three had a hire date of July, 2018 with no semiannual competency assessment for the first year of testing. Moderate complexity testing person four had a hire date of February 2018 with no semiannual competency assessment for the first year of testing. Moderate complexity testing person five had a hire date of August 22,

	2017 with no semiannual competency assessment for the first year of testing. 3. Interview of the respiratory therapy department director conducted on June 11, 2018 at 9:47 AM confirmed there were no annual competency assessments conducted in 2018 for moderate complexity testing persons, six and seven.
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 of the CMS-209 Laboratory Personnel report, review of personnel files and confirmed in interview, the Technical Consultant failed to evaluate and document the competency assessment for two of seven moderate complexity testing personnel in 2018. The findings included: 1. Review the CMS at 209 laboratory personnel report found seven testing personnel listed as performing moderate complexity testing in the blood gas laboratory. 2. Review of personnel records found no annual competency assessment performed in 2018 for two of seven testing personnel. Moderate complexity testing Testing person six had a hire date of January 27, 2015 moderate complexity testing testing person seven had a hire date of April 28, 2015 3. Interview of the respiratory therapy department director conducted on June 11, 2018 at 9:47 AM confirmed there were no annual competency assessments conducted in 2018 for moderate complexity testing persons, six and seven.
D6061	CLINICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1419(c) The clinical consultant must ensure that reports of test results include pertinent information required for specific patient interpretation. This STANDARD is not met as evidenced by: Based on review of patient test records, and interview with facility personnel, the clinical consultant failed to ensure that blood gas test results included the appropriate reference intervals (ranges) for specific patient interpretation. (see D 5807)
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 seven of seven testing personnel performing blood gas testing using the Abbott i-STAT (see 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 CMS-209 laboratory personnel report, and staff interview, the laboratory failed to have documentation of education and training to qualify seven of seven testing personnel performing blood gas testing using the Abbott i-STAT (see D6065).
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of laboratory policies, review of patient transfusion records, and confirmed in interview of facility personnel, the laboratory director failed to provide overall management and direction to the laboratory (refer to D6094 and D6096).
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the facility records, and staff interview, it was revealed the laboratory director failed to ensure a quality assessment plan identified and corrected problems in analytic systems (refer to D5793)
D6096	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7) The laboratory director must ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established

	performance characteristics are identified. This STANDARD is not met as evidenced by: Based on review of transfusion records and staff interview, it was revealed the laboratory director failed to ensure problems were resolved with the ordering transfusion reaction investigations and transfusion reaction documentation of blood products (refer to D3025, D5207, D5559, and D5793).
D6118	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(5) The technical supervisor is responsible for resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications. This STANDARD is not met as evidenced by: Based on review of transfusion records and staff interview, it was revealed the technical supervisor failed to ensure problems were resolved with the ordering transfusion reaction investigations and transfusion reaction documentation of blood products (refer to D3025, D5207, D5559, and D5793).