Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2094665	06/22/2018
Name of Provider or Supplier	**Street Address, City, State**	
The Medical Resort At Sugarland	1803 Westcott Avenue, Sugar Land, 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	An entrance conference was held 06/22/2018 with testing personnel one. The survey process was discussed. An opportunity for questions and comments was given. The laboratory was found out of compliance with the CLIA (Clinical Laboratory Improvement Amendments) regulations. Immediate jeopardy findings were identified. The conditions not met were: D2000 - 42 C.F.R. 493.801 Condition: Enrollment and Testing of Samples (proficiency testing) D5016 - 42 C.F.R. 493.1210 Condition: Routine chemistry; D5400 - 42 C.F.R. 493.1250 Condition: Analytic systems; D5800 - 42 C.F.R. 493.1290 Condition: Postanalytic 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; An exit conference was held by telephone on 06/22/2016 with the laboratory director, the clinical operations supervisor, and the laboratory supervisor. The exit conference attendees were advised the laboratory was out of compliance and advised of conditions and deficiencies found during the survey. An opportunity for questions and comments was provided. On June 25, 2018 the laboratory director submitted a letter stating the laboratory would not voluntarily cease testing at this time.
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: Based on direct observation, review of the laboratory's submitted test menu, review of the CMS (Centers for Medicare and Medicaid Services) 155 report, review of manufacturer's "Technical Bulletin for Proficiency Testing on the i-STAT System, attempted review of laboratory proficiency testing records, and interview of facility personnel it was revealed that the laboratory failed to enroll in a proficiency testing program for each of the specialties and subspecialties for which it seeks certification (chemistry) for 2017 and 2018. The findings were: 1. Review of the laboratory's submitted test menu on June 22, 2018 revealed the laboratory performs arterial blood gas testing using the Abbott i-STAT point of care analyzer. 2. Based on surveyor observation on 06/22/2018 at 0915 hours in the laboratory refrigerator during the initial tour of the laboratory revealed the following test cartridges available for use in patient testing. Abbott i-STAT G3+ arterial blood gas 3. Review of the CLIA FDA Database revealed that Abbott i-STAT G3+ test cartridges for arterial blood gas are labeled as moderate complexity. 4. Review of the CMS 155 report revealed that no proficiency testing scores had been reported to the Centers for Medicare and Medicaid Services (CMS). 5. Review of Abbott i-STAT Technical Bulletin Proficiency Testing on the i-STAT System (Art. 714262-00AD, Rev. Date: 12-Feb-15) stated under "CLIA Requirements for Proficiency Testing": "Moderate Complexity Tests: CLIA regulation Subpart H - Participation in Proficiency Testing requires a laboratory to enroll in a proficiency testing program approved by the Centers for Medicare and Medicaid Services (CMS) for its primary test system or that system used at its primary site. The laboratory must participate successfully as defined by the criteria defined in Subpart I - Proficiency Testing Programs." and; "For CLIA regulated analytes, proficiency (PT) programs must provide three separate shipments during the year that include five challenges for each analyte or test. Laboratories must comply with the CLIA requirements and those of their accrediting organization when testing PT samples" 6. Attempted review of proficiency testing records during the onsite survey on June 22, 2018 revealed no records were available for review that would document the laboratory being enrolled in a proficiency testing program in 2017 or 2018 for chemistry. 7. Review of patient test results revealed that laboratory performed 157 arterial blood gas patient tests since from December 2016 to June 22, 2018 (the date of the survey). 8. An interview with testing person number one (as listed on Form CMS-209) who is also the laboratory supervisor on June 22, 2018 at 0910 in the laboratory during the initial tour of the laboratory confirmed the findings. She revealed that the instrument manufacturer told them they did not have to perform proficiency testing. Key: CLIA - Clinical Laboratory Improvement Amendments FDA - Food and Drug Administration
D5016	ROUTINE CHEMISTRY CFR(s): 493.1210 If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1267, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on direct observations, review of laboratory policy, review of manufacturer's instructions, review of patient test records, review of environmental records, and confirmed in interview of facility personnel, the laboratory did not meet the requirements for routine chemistry as evidenced by: 1. The laboratory failed to have a

	policy that was approved and signed by the laboratory director that instructed testing personnel on all aspects of the testing procedure. (refer to D5403-A and D5403-B) 2. The laboratory failed to follow the manufacturer's instructions to verify the transit temperature of Abbott i-STAT G3+ test cartridges. (refer to D5411) 3. The laboratory failed to have a mechanism in place to monitor the room temperature and humidity of the laboratory. (refer to D5413) 4. The laboratory failed to perform verification studies on the Abbott i-STAT point of care analyzer used for arterial blood gases prior to patient testing in December 2016. (refer to D5421) 5. The laboratory failed to have a policy that would monitor quality control to detect immediate errors and errors over time. (refer to D5441) 6. The laboratory failed to perform at least one level of quality control each eight hours of patient testing or to develop an IQCP (Individualized Quality Control Plan) to reduce the frequency of quality control testing. (refer to D5537) 7. The laboratory failed to have a policy that would identify and correct errors in the analytic systems. (refer to D5791)
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on direct observations, review of laboratory policy, review of manufacturer's instructions, review of patient test records, review of environmental records, and confirmed in interview of facility personnel, the laboratory failed to monitor and evaluate the overall quality of its analytic systems as evidenced by: 1. The laboratory failed to have a policy that was approved and signed by the laboratory director that instructed testing personnel on all aspects of the testing procedure. (refer to D5403-A and D5403-B) 2. The laboratory failed to follow the manufacturer's instructions to verify the transit temperature of Abbott i-STAT G3+ test cartridges. (refer to D5411) 3. The laboratory failed to have a mechanism in place to monitor the room temperature and humidity of the laboratory. (refer to D5413) 4. The laboratory failed to perform verification studies on the Abbott i-STAT point of care analyzer used for arterial blood gases prior to patient testing in December 2016. (refer to D5421) 5. The laboratory failed to have a policy that would monitor quality control to detect immediate errors and errors over time. (refer to D5441) 6. The laboratory failed to perform at least one level of quality control each eight hours of patient testing or to develop an IQCP (Individualized Quality Control Plan) to reduce the frequency of quality control testing. (refer to D5537) 7. The laboratory failed to have a policy that would identify and correct errors in the analytic systems. (refer to D5791)
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: A. Review of laboratory policy and interview of facility personnel found that the laboratory director failed to approve, sign and date one of one laboratory policies available to testing personnel for performance of arterial blood gas (ABG) testing using the Abbott i-STAT point of care analyzer. The findings were: 1. Review of laboratory policy titled, "Arterial Blood Gas Procedure" Policy number "H-RC 02-001) found no documentation of the approval (including signature and date of approval) by the current laboratory director. 2. Interview of testing personnel one (as listed on Form CMS-209) who is also the laboratory supervisor on 06/22/2018 at 1100 hours in the Assistant Director of Nursing's office confirmed the findings. B. Review of laboratory policy and interview of facility personnel found that the laboratory's policy for "Arterial Blood Gas Procedure" failed to include policies and procedures for patient preparation, step-by-step test performance, preparation of controls, calibration and calibration verification procedures, instrument reportable range, quality control procedures, corrective action protocols, normal range values, critical or panic value alert protocol, result reporting, and what to do in the event the instrument were to become inoperable. The findings were: 1. Review of laboratory policy titled "Arterial Blood Gas Procedure" Policy number "H-RC 02-001), no laboratory director approval signature or date, revealed no or incomplete information available to the testing person for: a. Patient preparation: (policy failed to include specimen rejection criteria); b. Step-by-step test performance of the procedure (to include interpretation of results); c. Preparation of calibrators and controls; d. Calibration and calibration verification procedures; e. Reportable range of the analyzer; f. Quality control procedures; g. Corrective action protocols; h. Patient normal range values; i. Critical or panic alert procedures; j. Result reporting; k. Course of action to take when the instrument becomes inoperable. 2. Interview of testing personnel one (as listed on Form CMS-209) who is also the laboratory supervisor on 06/22/2018 at 1100 hours in the Assistant Director of Nursing's office confirmed the findings.
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 direct observation, review of manufacturer's instructions, review of environmental records from November 2016 to June 22, 2018 (the day of the survey), and confirmed in interview of facility personnel, the laboratory failed to follow the manufacturer's instructions to verify the shipping temperature of test cartridges for the Abbott i-STAT G3+ testing cartridges used for arterial blood gas testing. The findings were: 1. Based on direct observation in the laboratory on June 22, 2018 at 0915 hours during the initial tour of the laboratory, the laboratory had the following test cartridges available for patient testing: Abbott i-STAT G3+ Lot D18065 Received date: 05-17-2018 2. Review of the manufacturer's instructions for the Abbott i-STAT (Art: 714376-OOS, Rev. Date 23-Feb1-15) in chapter 14 "Quality Control," stated, "Verify that the transit temperatures were satisfactory using the four-window temperature indicator strip included in the shipping container." 3. In an interview with testing personnel one (as listed on Form CMS-209) who is also the laboratory supervisor in the Assistant Director of Nursing's office on 06/22/2018 at 1130 confirmed the findings. She revealed that she visually checked the thermometers, but did not document the recording or save the thermometers.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on surveyor observation, review of manufacturer's instructions, and confirmed in interview of facility personnel, the laboratory failed to monitor the operating temperature and humidity of the laboratory where the i-STAT chemistry analyzer was used. The findings were: 1. Surveyor observation made in the laboratory during the initial tour of the laboratory at 09:15 hours revealed no means of monitoring the temperature or humidity of the laboratory. 2. Review of the i-STAT System Manual (Art: 714336-OOM, Rev. Date 07-Mar-13) under "Specifications" stated: "Operating Temperature: 16-30 degrees Celsius (61-86 degrees Fahrenheit for i-STAT cartridge testing" and; "Relative Humidity: 90% (maximum) non-condensing" 3. An interview of testing personnel one (as listed on Form CMS-209) who is also the laboratory supervisor confirmed the findings. She confirmed that she was monitoring the refrigerator temperature but the not the room temperature and humidity. Key: CMS - Centers for Medicare and Medicaid Services
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 review of manufacturer system performance verification protocol, attempted review of laboratory verification records for the Abbott i-STAT point of care analyzer, and confirmed in interview of facility personnel, the laboratory failed to perform an instrument verification that included accuracy, precision, reportable range, and that verified patient normal ranges prior to performing patient testing for arterial blood gases on the Abbott i-STAT point of care analyzer. The findings were: 1. Review of the Abbott i-STAT System Performance Verification Protocol (720619 /Rev. D, DCP-00000049, Effective Date: 22 June 2016) stated, "Purpose: This verification protocol provides an efficient means to collect statistically valid data that can be used to assess the performance of each handheld and each sensor type found in cartridges containing tests for chemistries, blood gases and hematocrit that will be used for i-STAT testing. The following studies are described in this protocol: Verification of Accuracy Across the Reportable Range (Reportable Range), Precision and Method Comparison. Data from the Method Comparison studies can be used to verify reference ranges." 2. Based on review of laboratory records, the laboratory performed arterial blood gases (ABGs) on the Abbott i-STAT point of care analyzer which comprised of the following tests: pH PCO2 PO2 BEecf HCO3 TCO2 sO2 3. Verification records for the Abbott i-STAT point of care analyzer were requested at 1130 hours but not provided. The laboratory failed to perform an instrument verification that verified: -Accuracy -Precision -Reportable Range -Patient Normal Range 4. Interview of testing personnel number one (as listed on Form CMS-209) who is also the laboratory supervisor confirmed the findings. She revealed that the laboratory uses "the manufacturer's normal ranges" and that there were no other verification records available for review other than when quality control was tested one time in November 2016. Key: PCO2 - partial pressure or carbon dioxide PO2 - partial pressure of oxygen BEecf - base excess in the extracellular fluid compartment HCO3 - bicarbonate TCO2 - total carbon dioxide sO2 - oxygen saturation CMS - Centers for Medicare and Medicaid Services
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: Based on a review of laboratory policy, attempted review of quality control records from December 2016 to June 22, 2016 (the day of the survey), and confirmed in interview, the laboratory failed to have a quality control plan that would detect

	immediate errors and errors over time for arterial blood gas (ABG) testing. The findings were: 1. Attempted review of the laboratory's quality control records from December 2016 to June 22, 2018 (the day of the survey) revealed the laboratory did not perform at least one level of quality control each eight hours of patient testing. The laboratory could not detect immediate errors. 2. Attempted review of the laboratory's quality control records from December 2016 to June 22, 2018 (the day of the survey) revealed the laboratory did not perform at least one level of quality control each eight hours of patient testing. The laboratory did not accumulate quality control data, so therefore could detect errors over time. 3. In an interview at 1300 hours on 06 /22/2018 in the Assistant Director of Nursing's office, the laboratory supervisor confirmed the findings.
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 review of the laboratory's quality control records, review of patient test records from December 2016 to June 22, 2016 (the day of the survey), and confirmed in interview of facility personnel, revealed the laboratory failed to perform at least 1 level of quality control testing each eight hours of patient testing. The findings included: 1. Review of the laboratory's quality control testing from December 2016 to June 22, 2018 (the day of the survey) revealed the laboratory performed two levels of quality control testing on November 30, 2016. 2. When asked if the laboratory developed an IQCP (Individualized Quality Control Plan) to reduce the frequency of quality control testing, testing personnel one (as listed on Form CMS-209) stated, "No." 3. Review of patient results from December 2016 to June 22, 2018 (the day of the survey) revealed the laboratory performed 157 arterial blood gas patient tests when the laboratory failed to perform at least one level of quality control each eight hours of patient testing (see patient alias report). 4. An interview of testing personnel one (as listed on Form CMS-209) who is also the laboratory supervisor on 06/22/2018 at 1400 hours in the Assistant Director of Nursing's office confirmed the findings. She confirmed that the November 2016 quality control run was the only time external quality control testing was performed. Key: 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: Based on surveyor observations, review of quality control records, review of environmental records, review of patient reports, and confirmed in interview of

	facility personnel, the laboratory failed to have a policy that would identify and correct errors in the analytic systems as evidenced by: 1. The laboratory failed to have a quality assurance mechanism in place that would identify and correct that the laboratory's policies and procedures were not approved, signed, and dated by the current laboratory director. (refer to D5403-A) 2. The laboratory failed to have a quality assurance mechanism in place that would identify and correct that the laboratory's policy for arterial blood gas testing did not provide instructions for testing personnel in all aspects of the testing procedure. (refer to D5403-B) 3. The laboratory failed to have a quality assurance mechanism in place that would identify and correct that the laboratory failed to monitor the room temperature and humidity of the laboratory. (refer to D5413) 4. The laboratory failed to have a quality assurance mechanism in place that would identify and correct that the laboratory failed to perform verification studies on the Abbott i-STAT point of care analyzer used for arterial blood gases prior to patient testing in December 2016. (refer to D5421) 5. The laboratory failed to have a quality assurance mechanism in place that would identify and correct that the laboratory failed to have a policy to monitor quality control to detect immediate errors and errors over time. (refer to D5441) 6. The laboratory failed to have a quality assurance mechanism in place that would identify and correct that the laboratory failed to perform at least one level of quality control each eight hours of patient testing or develop an IQCP (Individualized Quality Control Plan) to reduce the frequency of quality control testing. (refer to D5537)
D5800	POSTANALYTIC SYSTEMS CFR(s): 493.1290 Each laboratory that performs nonwaived testing must meet the applicable postanalytic systems requirements in 493.1291 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 postanalytic systems and correct identified problems as specified in 493. 1299 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on chart review of patient results and confirmed in interview of facility personnel revealed the laboratory failed to monitor and evaluate the quality of post analytic systems as evidenced by: 1. The laboratory failed to ensure the name of the facility and the address where testing was performed was included on each on patient final reports. (refer to D5805) 2. The laboratory failed to ensure that the reference ranges available to healthcare providers were validated and accurately reflect the type of testing performed by the laboratory. (refer to D5807) 3. The laboratory failed to establish a quality assurance program that would identify and correct errors in post analytic systems. (refer to D5891)
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the

	condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: A. Based on chart review of patient results and confirmed in interview of facility personnel revealed the laboratory failed to have the name and address of the facility where patient testing was performed on each patient report. The findings were: 1. Random review of patient charts from June 2018 revealed 4 of 4 patient results did not contain the name and address of the facility where the testing was performed. 2. The findings were confirmed in a telephone interview of testing personnel one (as listed on Form CMS-209) who is also the laboratory supervisor on June 25, 2018. B. Based on chart review of patient results from December 10, 2016 to June 22, 2018 (the day of the survey) and confirmed in interview of facility personnel, the laboratory failed to ensure patient final reports had at least two unique identifiers. The findings were: 1. Random review of patient reports from December 10, 2016 to June 22, 2018 found the following six patient reports finalized when the report did not have at least 2 unique identifiers: Date: 03/07/2017 @ 23:56 [Patient ID] No other identifier Date: 04 /11/2017 @ 09:58 [Patient Name] No other identifier Date: 06/20/2017 @ 04:21 [Patient ID] No other identifier Date: 06/20/2017 @ 05:32 [Patient ID] No other identifier Date: 06/21/2017 @ (time undecipherable) Patient ID: (undecipherable) [Patient last name only] Date: 08/03/2017 @ 02:49 [Patient ID] No other identifier 2. An interview with testing personnel one (as listed on Form CMS-209) on 06/25/2018 by telephone confirmed the findings.
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 review of the laboratory's instrument verification records, review of the Abbott i-STAT operator's manual, review of patient final reports, and confirmed in interview of facility personnel, the laboratory failed to ensure validated patient normal ranges were available to ordering and/or treatment healthcare providers. The findings were: 1. The laboratory performs arterial blood gas testing on the Abbott i-STAT point of care analyzer using arterial blood as the sample type. 2. Attempted review of the laboratory's instrument verification records for the Abbott i-STAT point of care chemistry analyzer revealed the laboratory had not performed a verification study for the analyzer prior to testing patients in December 2016. 3. Review of the Abbott i-STAT operator's manual (Art: 714364-00N, Rev. Date 10-Feb-15) listed the following reference ranges for venous and arterial blood: ANALYTE UNIT ARTERIAL VENOUS pH none 7.35-7.45 7.31-7.41 PCO2 mmHg 35-45 41-51 PO2 mmHg 80-105 none HCO3 mmol/L 22-26 23-28 TCO2 mmol/L 23-27 24-29 sO2 % 95-98 none 4. Random review of four patient reports from June 2018 revealed the following reference ranges were listed on the patient reports: ANALYTE UNIT REFERENCE RANGE pH none 7.310-7.410 PCO2 mmHg 41.0-51.0 PO2 mmHg 80-105 HCO3 mmol/L 23-28 TCO2 mmol/L 24-29 sO2 % 95-98 5. The reference range for pH matched the manufacturer's reference range for venous blood. The laboratory performs patient testing on arterial blood. 6. The reference range for PCO2 matched

	the manufacturer's reference for venous blood. The laboratory performs patient testing on arterial blood. 7. The reference range for HCO3 matched the manufacturer's reference range for venous blood. The laboratory performs patient testing on arterial blood. 8. The reference range for TCO2 matched the manufacturer's reference range for venous blood. The laboratory performs patient testing on arterial blood. 9. An interview with testing personnel one (as listed on Form CMS-209) who is also the laboratory supervisor on 06/22/2018 at 1400 hours in the Assistant Director of Nursing's office confirmed the findings. She confirmed the laboratory uses manufacturer's reference ranges but agreed the laboratory had not verified the manufacturer's patient normal ranges were appropriate for the facility's patient population. Key: PCO2 -partial pressure of carbon dioxide PO2 - partial pressure of oxygen HCO3 - bicarbonate TCO2 - total carbon dioxide sO2 - oxygen saturation
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: Based on review of patient results, and confirmed in interview of facility personnel, the laboratory failed to have a policy that would identify and correct errors in the post analytic systems as evidenced by: 1. The laboratory failed to have a quality assurance mechanism in place that would identify and correct that the name and address of the facility where testing was performed was included on the patient final report. (refer to D5805) 2. The laboratory failed to have a quality assurance mechanism in place that would identify and correct that the reference ranges available to the healthcare providers were validated and accurate for the testing performed by the laboratory. (refer to D5807)
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 surveyor observations, review of laboratory policy, review of manufacturer's instructions, review of environmental records, review of quality control records, review of patient reports, and confirmed in interview of facility personnel the laboratory director failed to provide overall management and direction of laboratory services. (refer to D6007, D6013, D6015, D6020, D6021, D6022, D6029, D6031, and D6032)
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) 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)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by: Based on review of laboratory policy, review of manufacturer's instructions, review of patient results, and confirmed in interview of facility personnel, the laboratory director failed to ensure quality laboratory services for testing performance for the analytic phases of testing as evidenced by: 1. The laboratory director failed to approve, sign and date one of one laboratory policies available to testing personnel for performance of arterial blood gas (ABG) testing using the Abbott i-STAT point of care analyzer. (refer to D5403-A) 2. The laboratory director failed to implement a policy that included procedures for patient preparation, step-by-step test performance, preparation of controls, calibration and calibration verification procedures, instrument reportable range, quality control procedures, corrective action protocols, normal range values, critical or panic value alert protocol, result reporting, and what to do in the event the instrument were to become inoperable. (refer to D5403-B) 3. The laboratory director failed to ensure the laboratory verified the transit of Abbott i-STAT G3+ testing cartridges. (refer to D5411) 4. The laboratory director failed to ensure the laboratory monitored the room temperature and humidity of the laboratory. (refer to D5413) 5. The laboratory director failed to ensure instrument verification studies were performed on the Abbott i-STAT point of care analyzer prior to patient testing. (refer to D5421) 6. The laboratory director failed to establish a quality control plan that would detect immediate errors and errors over time. (refer to D5441) 7. The laboratory director failed to ensure at least one level of quality control material was tested each eight hours of patient testing on the Abbott i-STAT point of care analyzer or perform and IQCP (Individualized Quality Control Plan) to reduce the frequency of quality control testing. (refer to D5537) 8. The laboratory director failed to establish a quality assurance plan that would identify and correct errors in the analytic systems. (refer to D5791 and D5891)
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on attempted review of verification studies for the Abbott i-STAT point of care analyzer for arterial blood gas (ABG) and interview with facility personnel, the laboratory director failed to ensure verification studies for accuracy, precision, reportable range, and patient normal ranges were complete prior to patient testing in December 2016. (refer to D5421)

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 each specialty and subspecialty (chemistry) for which it seeks certification. (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 review of laboratory records, review of patient test records, and confirmed in interview of facility personnel, the laboratory director failed to ensure a quality control policy was developed to instruct testing persons on quality control performance and acceptance. (refer to D5441 and D5537)
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 laboratory policies, quality control records, patient records, and confirmed in staff interview, the laboratory director failed to ensure quality assessment policies were established that would instruct testing persons on how to identify and correct errors in the analytic and post analytic phases of the patient testing process. (refer to D5791 and D5891)
D6022	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 and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on surveyor observations, review of laboratory policy, review of manufacturer's instructions, review of quality control records, review of instrument verification records, and confirmed in interview, the laboratory director failed to ensure that quality control and quality assessment programs are established and maintained to identify, monitor, and correct failures in quality of testing as they occurred. (refer to D5391, D5441, D5537, D5791, and D5891)
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's personnel records, and interview with facility personnel, the laboratory director failed to ensure that 8 of 8 testing personnel had the appropriate documentation of education and appropriate training required to qualify to perform moderate complexity testing. (Refer to D6065 and D6066).
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 procedure manual and interview of facility

	personnel, the laboratory director failed to ensure approved procedures for all aspects of arterial blood gas (ABG) testing was available to all testing personnel. (refer to D5403)
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of testing personnel records and staff interview, the laboratory director failed to specify the duties of each consultant and each testing person engaged in all phases of testing, which examinations and procedures each individual is authorized to perform, whether supervision is required, or whether consultant or director review is required prior to reporting patient test results for 8 of 8 testing personnel.
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 a review of the Form CMS-209 Laboratory Personnel Report and confirmed in interview, the laboratory failed to have appropriate personnel to ensure technical oversight of the laboratory. (refer to D6035)
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory

	training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form CMS-209 and confirmed in interview of facility personnel, the laboratory failed to provide documentation of qualified technical consultant. The findings were: 1. A review of the CMS-209 signed by the laboratory director on 06/20/2018 revealed that the position of technical consultant was blank. (refer to D6035) 2. Interview of the laboratory supervisor on 06 /22/2018 at 0930 hours in the Assistant Director of Nursing's office confirmed the findings. She confirmed the laboratory did not have a technical consultant.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel files and confirmed in interview of facility personnel, revealed a technical consultant had not performed testing personnel competency assessments. The findings were: 1. Review of the laboratory's personnel files revealed the competency assessments were performed by testing personnel one and then signed by the laboratory director. 2. On 06/22/2018 at 0930 hours in the Assistant Director of Nursing's office, the laboratory was asked to provide documentation of education that would qualify testing personnel one (as listed on Form CMS-209) who is also the laboratory supervisor that would qualify her as a technical consultant. 3. An interview with testing personnel one (as listed on Form CMS-209) who is also the laboratory supervisor confirmed the findings. She confirmed that she did not have a minimum of a bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution.

	She went on to say that she performed the direct observations for the competency assessments and that the laboratory director signed off on them.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on review of the laboratory's submitted Form CMS-209, review of the laboratory's personnel records, and confirmed in interview of facility personnel, the laboratory failed to have documentation of education to qualify 8 of 8 testing personnel (refer to D6065).
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form CMS-209, review of the laboratory's personnel files, and confirmed in interview of facility personnel, the laboratory failed to have documentation of education to qualify 8 of 8 testing personnel to perform moderate complexity testing. The findings were: 1. A review of the laboratory's submitted Form CMS-209 revealed the laboratory identified 8 testing personnel. 2. A review of the laboratory's personnel records revealed 8 of 8 testing personnel did not have documentation of education to qualify them to perform moderate complexity testing. The personnel education records for each of the testing persons were respiratory therapy state licensure. 3. Further review of the personnel records revealed no documentation of training for the 8 of 8 testing personnel. 4. An interview with testing personnel one (as listed on Form CMS-209) who is also the laboratory supervisor in the Assistant Director of Nursing's office on 06/22/2018 at 10: 00 hours confirmed the findings. She revealed that she had been trying to obtain the records but was having a hard time getting them. She went on to say that some of the testing persons were from foreign counties and they may not have those records. She went on to say that she trains the testing persons but has not been documenting the initial training. Key: CMS - Centers for Medicare and Medicaid Services