Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2030292	01/10/2019
Name of Provider or Supplier	**Street Address, City, State**	
Encompass Health Rehabilitation Hospital Of	13031 Wortham Center Drive, Houston, 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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended.
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 the laboratory verification records and confirmed in interview, the laboratory failed to perform complete verification studies for the patient testing on the Abbott iSTAT analyzer. (reference range, accuracy, reportable range) Findings were: 1. Random review of the laboratory patient records from October and November 2018 revealed the laboratory reported the following 9 analytes using the CG8+ I-STAT cartridges for the Abbott iSTAT analyzer using the following reference ranges. Glucose 70 - 199 mg/dL Ionized Calcium 1.12 - 1.32 mmol/L Sodium 138 - 146 mmol/L Hemoglobin (calculated) 12 - 15.5 g/dL Hematocrit 38 - 51% Potassium 3.5 - 4.9 mmol/L pH 7.35 - 7.45 pCO2 35 - 45 mmHg pO2 80 - 100 2. Review of the laboratory verification records revealed no documentation of a reference range study for 6 of 9 analytes. Glucose Ionized Calcium Sodium Hemoglobin (calculated)

	Hematocrit Potassium 3. Review of the laboratory verification records revealed no accuracy or reportable range assessment for 8 of 8 analytes. Glucose Ionized Calcium Sodium Hematocrit Potassium pH pCO2 pO2 4. An interview with the technical consultant via phone on 1/10/19 at 1130 hours confirmed the above findings. She acknowledged that the laboratory should have assessed the data for accuracy and reportable range and that a reference range study should have been done on all the analytes tested. Key: PCO2 -partial pressure of carbon dioxide PO2 - partial pressure of oxygen TCO2 - total carbon dioxide
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 the quality control (QC) reports, and verified by interview, the laboratory failed to monitor quality control over time for accuracy and precision for chemistry and hematology testing on the Abbott iStat analyzer. Findings were: 1. Review of the laboratory records revealed the laboratory performed chemistry and hematology testing on the Abbott iStat analyzer using the I-stat CG8+ cartridges. Glucose 70 - 199 mg/dL Ionized Calcium 1.12 - 1.32 mmol/L Sodium 138 - 146 mmol /L Hemoglobin (calculated) 12 - 15.5 g/dL Hematocrit 38 - 51% Potassium 3.5 - 4.9 mmol/L pH 7.35 - 7.45 pCO2 35 - 45 mmHg pO2 80 - 100 2. Review of the June to September 2018 quality control reports revealed no documentation of the laboratory monitoring the quality control over time for the above analytes. 3. An interview of the technical consultant via phone on 1/10/19 at 1205 hours in the conference room confirmed the above findings. Key: PCO2 -partial pressure of carbon dioxide PO2 - partial pressure of oxygen TCO2 - total carbon dioxide
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:

	A. Based on review of the manufacturer's instructions, laboratory policy, laboratory quality control records, and confirmed in interview, the laboratory IQCP failed to have documentation of a complete quality control study to include quality control material for each analyte and each day of the quality control plan prior to modifying the frequency of quality control testing for the iSTAT pH, pCO2 (partial pressure of carbon dioxide), and PO2 (partial pressure of oxygen) to every 30 days. Findings were: 1. Review of the laboratory quality control study of the IQCP revealed no documentation of the quality control study that included at least one level of quality control material every 8 hours for the iSTAT pH, pCO2 (partial pressure of carbon dioxide), and PO2 (partial pressure of oxygen) for 30 days. 2. An interview with the technical consultant via phone on 1/10/19 in the conference room confirmed the above findings. She was unaware the laboratory needed to perform the daily quality control every 8 hours for 30 days. B. Based on review of the manufacturer's instructions, laboratory policy, laboratory quality control records, and confirmed in interview, the laboratory IQCP failed to have documentation of a complete quality control study to include quality control material for each analyte and each day of the quality control plan prior to modifying the frequency of quality control testing for the iSTAT Ionized Calcium, Potassium, Glucose, Sodium and Hematocrit to every 30 days. Findings were: 1. Review of the laboratory quality control study of the IQCP revealed no documentation of the quality control study that included at least two levels of quality control material for the iSTAT Ionized Calcium, Potassium, Glucose, Sodium and Hematocrit for 30 days. 2. An interview with the technical consultant via phone on 1 /10/19 in the conference room confirmed the above findings. She was unaware the laboratory needed to perform the daily quality control for 30 days for the IQCP. key: IQCP - Individualized Quality Control Plan PCO2 -partial pressure of carbon dioxide PO2 - partial pressure of oxygen TCO2 - total carbon dioxide
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. Review of the Abbott i-STAT operator's manual (Art: 714364-00N, Rev. Date 10-Feb-15) revealed 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 TCO2 mmol/L 23-27 24-29 2. Random review of 9 of 9 patient reports with venous samples from October and November 2018 revealed documentation the laboratory used the arterial reference ranges on the patient reports. Patient ID: 11473 (11/30/18);110175 (11/20/18); 110175 (11/21/18); 105193 (10/30 /18); 111368 (10/25/18); 111237 (10/20/18); 111345 (10/15/18); 111304 (10/10/18); 110103 (10/8/18) ANALYTE UNIT REFERENCE RANGE pH none 7.35-7.45 PCO2 mmHg 35-45 TCO2 mmol/L 23-27 3. An interview with the technical consultant via phone on 1/10/19 at 1205 hours in the conference room confirmed the

	above findings. She acknowledged that the laboratory used the wrong reference range for the specimen type. Key: PCO2 -partial pressure of carbon dioxide PO2 - partial pressure of oxygen TCO2 - total carbon dioxide
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 quality assurance mechanism in place that would identify and correct problems in postanalytic systems. (refer to D5807)
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on review of the laboratory verification records and confirmed in interview, the laboratory director failed to ensure the laboratory performed complete verification studies for the testing on the Abbott iSTAT chemistry analyzer. Refer to 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: Review of quality control records and interview of facility personnel revealed the laboratory director failed to ensure that the quality control program was established and maintained for chemistry and hematology testing on the Abbott iSTAT analyzer. Refer to D5441, D5445
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2)

	The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on review of the laboratory verification records and confirmed in interview, the technical consultant failed to ensure the laboratory performed complete verification studies for the testing on the Abbott iSTAT chemistry analyzer. Refer to D5421
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on review of the laboratory policy, CMS form 209, personnel records for 2017 and 2018, and verified by interview, the Technical Consultant failed to perform the annual competency evaluations for 4 of 4 testing personnel in the year 2018. Findings were: 1. Review of the laboratory policy Personnel Training and Competency approved 12/1/2016 revealed "the laboratory director or technical consultant will assess the competency of each individual to fulfill the duties and responsibilities of their position using the laboratory competency assessment form and supporting documentation." 2. A review of the laboratory competency assessments for 2018 revealed documentation that testing person #1, who does not qualify as a technical consultant, performed annual competencies for 3 of 4 testing personnel for 2018. Testing person #1 has a high school diploma. Testing person #2, hired 02/2017 Testing person #3, hired 02/2017 Testing person #4, hired 03/2018 3. A review of the laboratory competency assessments for 2018 revealed documentation that testing person #2, who does not qualify as a technical consultant, performed annual competencies for 1 of 4 testing personnel for 2018. Testing person #2 has a high school diploma Testing person #1, hired 02/2017 4. An interview with the testing person #1 on 01/10/19 at 1020 hours in the conference room confirmed the above findings. She was unaware she did not qualify to perform the competencies for the laboratory staff. key: CMS - Centers for Medicaid and Medicare Services