Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2030292	06/15/2021
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.
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 operation manual, patient result records, CMS 116, and confirmed in an interview revealed the laboratory failed to follow the manufacturer's instruction to analyze glucose within 30 minutes and blood gas (pH, PCO2, PO2) within 10 minutes for 4 of 10 patients reviewed when performing testing with the i-STAT CG8+. The findings were: 1. Review of CMS 116 signed by the laboratory director (LD) on 6/11/2021 revealed chemistry tests performed by using Abbott i-STAT (SN#379739) CG8+ cartridges. 2. An interview with the technical consultant (TC) and the testing personnel #1 (TP#1) on 6/1/21 at 0910 am in the lab confirmed the collection system was Portex Arterial Blood Gas specimen collection devices with dry lithum balanced heparin. 3. Review i-STAT CG8+ Cartridge package insert (Art: 765792-00 Rev. C, Rev. Date: 30-Apr-2021) under Blood Collection Options and Test Timing (time from collection to cartridge fill) on p.6 revealed: "Analyte Ionized Calcium, pH, PCO2, PO2 Syringes With balanced heparin anticoagulant (or lithium heparin anticoagulant for pH, PCO2 and PO2 only) (syringe must be filled per

	manufacturer's recommendation) -Maintin anerobic conditions -Remix thoroughly before filling cartridge" Test timing 10 minutes" "Analyte Sodium, Potassium, Glucose, Hematocrit Syringes With balanced heparin anticoagulant or lithium heparin anticoagulant (syringe must be filled per manufacturer's recommendation) -Remix thoroughly before filling cartridge Test timing 30 minutes" 4. Random review of patient results from 6/1/20 to 6/1/21 revealed 1 of 10 patient samples were not run within 30 minutes test timing allowance for Glucose Date: 6/1/20 Patient:113508 Time drawn: 4:00pm Time ran: 4:39pm Time elapsed: 39 minutes 5. Random review of patient results from 6/1/20 to 6/1/21 revealed 3 of 10 patient samples were not run within 10 minutes test timing allowance for pH, PCO2, and PO2. Date: 7/15/20 Patient:109787 Time drawn: 4:40pm Time ran: 4:55pm Time elapsed: 15 minutes Date: 2/24/21 Patient:111653 Time drawn: 7:45am Time ran: 7:57am Time elapsed: 12 minutes Date: 3/12/21 Patient:114245 Time drawn: 5:05pm Time ran: 5:17pm Time elapsed: 12 minutes 6. An interview with the technical consultant (TC) and the testing personnel #1 (TP#1) on 6/1/21 at 1135 am in the conference room confirmed the above findings.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of the package insert, calibration verification records from 2019-2021, and confirmed in an interview revealed the laboratory failed to document calibration verification for 8 of 8 analytes (Sodium (Na), Potassium (K), Ionized Calcium (iCa), Glucose (Glu), Hematocrit (Hct), pH, PCO2, PO2) using the i-STAT CG8+ Cartridge every 6 months. The findings were: 1. Review i-STAT CG8+ Cartridge package insert (Art: 765792-00 Rev. C, Rev. Date: 30-APR-2021) under Calibration Verification on p.8 revealed "...The performance of this procedure is not a manufacturer's system instruction. However, it may be required by regulatory or accreditation bodies...." 2. Review of calibration verification records from 2019-2020 of i-STAT (SN#379739) revealed no documentation of calibration verification for 8 of 8 analytes (Sodium (Na), Potassium (K), Ionized Calcium (iCa), Glucose (Glu),

	Hematocrit (Hct), pH, PCO2, PO2) of the i-STAT every 6 months in 2019 and 2020. 3. Review of CMS 116 signed by the laboratory director (LD) on 6/11/2021 revealed the annual test volume of 1000. 4. An interview with the technical consultant (TC) and the testing personnel #1 (TP#1) on 6/1/21 at 1135 am in the conference room confirmed the above findings.