Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0675758	02/22/2022
Name of Provider or Supplier	**Street Address, City, State**	
Encompass Health Rehabilitation Hospital Of Humble	19002 Mckay Drive, Humble, 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. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
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 a review of the laboratory's verification records and staff interview, it was revealed that the laboratory failed to have documentation of verifying its patient normal ranges for 1 of 3 test cartridges used on the Abbott i-STAT analyzer. Findings include: 1. A review of the laboratory's verification records for the Abbott i-STAT

	analyzer (Serial number 411727) revealed verification studies were performed in August 2021. 2. The laboratory was asked to provide documentation of verifying the patient normal ranges for the iSTAT Chem 8+ cartridge on the Abbott i-STAT analyzer. No documentation was provided. 3. An interview with the technical consultant on 2/22/22 at 10:20 a.m. in the conference room, after review of the records, 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 a review of the laboratory's policies, the laboratory's calibration verification records from 2021, and staff interview, it was revealed that the laboratory failed to ensure 1 of 1 calibration verification was acceptable for all analytes run using the Chem 8+ cartridge on the Abbott i-STAT analyzer in 2021. Findings include: 1. A review of the laboratory's policy titled 'Calibration Verification' revealed the following: "Perform calibration for CHEM8+ and cTnI tests as indicated on the kit instructions. Evaluate results and compare to the value assignment sheets to ensure acceptability. If acceptability is not achieved, attempt to rerun the unacceptable level once and if a repeat failure is obtained, contact technical support." 2. A review of the laboratory's calibration verification records from August 2021 revealed the following analytes were tested on the Abbott i-STAT analyzer using the CHEM 8+ cartridge: BUN (blood urea nitrogen) CL (chloride) CREA (creatinine) GLU (glucose) HCT (hematocrit) ICA (ionized calcium) K (potassium) NA (sodium) TCO2 (Carbon dioxide) 3. Further review of the records revealed the laboratory failed to ensure the calibration verification was acceptable for the TCO2 analyte. TCO2 result: 52 Acceptable range: 37 - 50 *There was no documentation of an attempt to rerun the unacceptable TCO2 level. 4. An interview with the technical consultant on 2/22/22 at 10:40 a.m. in the conference room, after review of the records, confirmed the above findings.