

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2175151	(X3) Date Survey Completed 09/23/2021
Name of Provider or Supplier Encompass Health Rehabilitation Hospital Of Katy	Street Address, City, State 23331 Grand Reserve Drive, Katy, 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.
D5439	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>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.</p>

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's records from November 2019 to September 2021, a review of the laboratory's submitted CMS 116 application, and staff interview, it was revealed that the laboratory failed to have documentation of performing calibration verification every six months for testing using 2 of 2 Abbott i-STAT test cartridges (CHEM8+ and cTnI) in 2019, 2020, and 2021. Findings include: 1. A review of the laboratory's records revealed the facility started using the CHEM8+ cartridges on the Abbott i-STAT system in April 2020. The test cartridge contained the following tests: Sodium (Na) Potassium (K) Chloride (Cl) TCO2 Ionized Calcium (iCa) Glucose (Glu) Urea Nitrogen (BUN)/Urea Creatinine (Crea) Hematocrit (Hct) 2. A review of the laboratory's records revealed the facility started using the cTnI cartridges on the Abbott i-STAT system in November 2019. The test cartridge contained the following test: Troponin I (cTnI) 3. The Abbott i-STAT analyzer performed a single point calibration and two levels of control material were to be tested each day of patient testing. Thus, calibration verification was required. 4. Further review of the laboratory's records revealed calibration verifications were performed on the following 2 dates: CHEM8+ Calibration verification performed: 4/20 - No documentation of a calibration verification performed in 10/2020 or 4/2021 cTnI Calibration verification performed: 11/2019 - No documentation of a calibration verification performed in 5/2020, 11/2020, or 5/2021 5. A review of the laboratory's submitted CMS 116 application revealed an annual test volume of 60. 6. An interview with the technical consultant (as indicated on the CMS 209 form) on 9/23/21 at 11:00 a.m. in the conference room, after review of the records, confirmed the above findings.