Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D0885959	08/10/2021
Name of Provider or Supplier	**Street Address, City, State**	
Encompass Health Rehabilitation Hospital Of	9630 E Shea Blvd, Scottsdale, AZ	

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
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 lack of calibration verification documentation for blood gas testing and Chem8+ testing and interview with the testing personnel, the laboratory failed to perform and document calibration verification procedures as required. Findings include: 1. The laboratory performs Arterial Blood Gas (ABG) testing and Chem8+ testing on the I-Stat analyzer, with an approximate annual test volume of 900. 2. No documentation was presented for review to indicate the laboratory performed a

	calibration verification for ABG testing at least once every six months during 2019, 2020 and in 2021 through the date of the survey conducted on 8/10/21, 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. 3. No documentation was presented for review to indicate the laboratory performed a calibration verification for Chem8+ testing at least once every six months during 2020 and in 2021 through the date of the survey conducted on 8/10/21, 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. 4. The facility personnel acknowledged that a calibration verification was not performed every 6 months as indicated above on the I-stat analyzer as required for ABG and Chem8+ testing.
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: Based on lack of Quality Control (QC) documentation and interview with the facility personnel, the laboratory failed to perform and document control procedures using the number and frequency as required for testing performed in the specialties of Hematology and Chemistry. Findings include: 1. The laboratory began using the Chem8+ test cartridge performed on the i-Stat in January 2020. The Chem8+ panel includes the following analytes: Sodium, Potassium, Chloride, Ionized Calcium, Total CO2, Glucose, BUN, Creatinine, Hematocrit and Hemoglobin. The laboratory's approximate annual test volume for the Chem8+ test is 248 tests. 2. On the date of the survey, August 10, 2021, it was the policy of the laboratory to test 3 levels of QC material at the beginning of each month. 3. No daily QC documentation for Chem8+ testing was provided for review during the survey from the time period of January 1, 2020 through August 10, 2021, to indicate the laboratory performed at least two levels of control material of different concentrations each day of patient testing, as required. The laboratory had not established an Individualized Quality Control Plan (IQCP) for this test. 4. The facility personnel confirmed the laboratory did not perform and document external controls each day of patient testing as required since patient testing began on 1/01/2020.
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 lack of Quality Control documentation for review for Chem8+ testing performed on the I-stat analyzer, the laboratory director failed to ensure that the quality control program is established to assure the quality of laboratory services provided. See D5445 for findings.
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 testing personnel competency assessments for 2020 pertaining to blood gas testing and interview with the facility personnel, the technical consultant failed to indicate by signature and date that any of the assessments performed on six out of six testing personnel were evaluated by the technical consultant indicated on the CMS-209 form (Laboratory Personnel Report). Findings include: 1. The competency assessment evaluations were being signed off by one of the testing personnel indicated on the CMS-209 form with no indication of competency assessment being performed by the technical consultant for moderate complexity testing under the specialty of Chemistry. 2. The annual competency assessment form from 2020 presented for review for one testing personnel failed to include the signature of the individual who performed the competency evaluation. The form was only signed by the testing personnel who was being evaluated and dated 2/06/2020. 3. The facility personnel acknowledged that the competency assessments were being performed by the testing personnel and not the Technical Consultant.