Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1064913	04/06/2021
Name of Provider or Supplier	**Street Address, City, State**	
Encompass Health Rehabilitation Of Sugar Land	1325 Highway 6, Sugar Land, 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.
D1002	REPORTING OF SARS-CoV-2 TEST RESULTS During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on a review of the product insert for the Abbott ID NOW COVID-19 test, a review of the laboratory's policies, a random review of patient test records from February 2021 to April 2021, and staff interview, it was revealed that the laboratory failed to have documentation of reporting negative COVID-19 test results to the local and/or state health department for 15 of 15 patients whose specimens were run using the Abbott ID NOW COVID-19 assay. Findings include: 1. A review of the product insert for the Abbott ID NOW COVID-19 test (IN190000 Rev 6, 09/2020) revealed the following: "Testing facilities within the United States and its territories are

	required to report all results to the appropriate public health authorities." 2. A review of the laboratory's policy titled 'COVID-19 Emergency State Rules and Reporting' revealed the following: "Every public or private entity that is utilizing an FDA-approved test, including an emergency use authorization test, for human diagnostic purposes of COVID-19, shall submit to DSHS, as well as to the local health department, daily reports of all test results, both positive and negative." 3. A random review of patient test records from February 2021 to April 2021 revealed the laboratory failed to have documentation of reporting negative COVID-19 test results to the local and/or state health department for the following 15 patients whose specimens were run using the Abbott ID NOW COVID-19 assay: Patient ID: 122022 Run: 2/12/21 COVID-19 test result: Negative Patient ID: 122063 Run: 2/20/21 COVID-19 test result: Negative Patient ID: 416606 Run: 2/22/21 COVID-19 test result: Negative Patient ID: 122119 Run: 2/26/21 COVID-19 test result: Negative Patient ID: 410977 Run: 2/28/21 COVID-19 test result: Negative Patient ID: 122153 Run: 3/2/21 COVID-19 test result: Negative Patient ID: AC0000122159 Run: 3/5/21 COVID-19 test result: Negative Patient ID: 122180 Run: 3/10/21 COVID-19 test result: Negative Patient ID: 122240 Run: 3/11/21 COVID-19 test result: Negative Patient ID: AC0000122212 Run: 3/14/21 COVID-19 test result: Negative Patient ID: 122225 Run: 3/15/21 COVID-19 test result: Negative Patient ID: 00415413 Run: 3/19 /21 COVID-19 test result: Negative Patient ID: 122292 Run: 3/21/21 COVID-19 test result: Negative Patient ID: 00415440 Run: 3/24/21 COVID-19 test result: Negative Patient ID: 416776 Run: 4/5/21 COVID-19 test result: Negative 4. An interview with the nurse manager on 4/6/21 at 1:00 p.m. in the conference room, after review of the records, stated that only positive COVID-19 results are reported. This confirmed the above findings. Key: DSHS = Department of State Health Services
D2089	ROUTINE CHEMISTRY CFR(s): 493.841(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3)The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, a review of the laboratory's American Proficiency Institute (API) proficiency testing records for 2020, a review of the Performance Review and Corrective Action Documentation form, and staff interview, it was revealed that the laboratory failed to ensure proficiency testing results were returned within the required time frame for 1 of 3 Chemistry testing events for 2020, resulting in a score of 0% for all analytes, constituting unsatisfactory performance. Findings include: 1. A review of the laboratory's policy titled 'Proficiency Testing' revealed the following: "Results may be submitted online, by fax or email. Ensure any deadlines for submission are met." 2. A review of the laboratory's API testing records for the 2020 Chemistry- Core- 3rd Event revealed the laboratory failed to submit the data on time, resulting in unsatisfactory scores for the following analytes: Calcium, Ionized 0% Chloride 0% Creatinine 0% Glucose 0% Hematocrit 0% Hemoglobin 0%

	Potassium 0% Sodium 0% TCO2 0% Urea Nitrogen 0% 3. Further review of the Performance Review and Corrective Action Documentation form for the above listed event, revealed the following notes by the laboratory director: "Run by due date- Not submitted- no patients affected." 4. An interview with the laboratory director on 4/6 /21 at 10:25 a.m. in the conference room, after review of the records, confirmed the above findings.
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 a review of the laboratory's Individualized Quality Control Plan (IQCP) studies, a review of the laboratory's IQCP Quality Assessment Review Form, and staff interview, it was revealed that the laboratory's IQCP failed to have documentation to support the modification in quality control testing for 2 of 2 cartridges (Chem 8 and Troponin) run on the Abbott i-STAT analyzer. Findings include: 1. A review of the laboratory's IQCP studies for the Abbott i-STAT analyzer revealed the laboratory modified the frequency of quality control testing for the Chem 8 and Troponin cartridges to the following: - with each shipment - with each new lot - every 30 days 2. Further review of the laboratory's IQCP studies revealed the laboratory's evidence to support the modification in control testing: a) Chem 8 cartridges Level 1 and Level 3 controls were run once a day for 10 days b) Troponin cartridges Level 1 and Level 3 controls were run once a day for 10 days 3. A review of the laboratory's IQCP Quality Assessment Review Form from 6/3/20, signed by the laboratory director, revealed the following notation: "Note: Initial study covered 10 days of continuous QC- we have now run QC monthly and on new cartridges and found no outliers- thus covered multiple operators and multiple QC lots- in addition, this is over several CLEW updates. Therefore, continued approval to run QC monthly and on new lots /shipments." 4. The laboratory director was asked to provide documentation of performing quality control testing each day for at least the length of the modification (30 days). No documentation was provided. 5. An interview with the laboratory director on 4/6/21 at 11:50 a.m. in the conference room, after review of the records, confirmed the above findings. Key: QC = Quality Control
D6017	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(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)(4)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute (API) proficiency testing results from 2020 and staff interview, it was revealed the laboratory director failed to ensure proficiency testing results were returned within the required timeframe (refer to D2089).
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on a review of the laboratory's submitted CMS 209 form, a review of the laboratory's personnel records, and staff interview, it was revealed that the laboratory director failed to specify in writing the responsibilities and duties for 1 of 1 clinical consultant. Findings include: 1. A review of the laboratory's submitted CMS 209 form, signed by the laboratory director on 4/5/21, identified one clinical consultant. 2. A review of the laboratory's personnel records revealed the laboratory director failed to have written responsibilities and duties for the clinical consultant. 3. An interview with the laboratory director on 4/6/21 at 9:30 a.m. in the conference room, confirmed the above findings.
D6053	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 semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, a review of the laboratory's submitted CMS 209 form, a review of the laboratory's personnel records, and staff interview, it was revealed that the laboratory failed to have documentation of the technical consultant performing competency assessments, at least semiannually during the first year of testing, for 6 of 14 testing personnel. Findings include: 1. A review of the laboratory's policy titled 'Personnel Training and Competency' revealed the following: "Each employee will be given an evaluation for competency semi-annually during the first year and annually thereafter." 2. A review of the laboratory's submitted CMS 209 form (signed by the laboratory director on 4/5/21) revealed the laboratory identified 14 testing personnel performing moderate complexity testing. 3. A review of the

	laboratory's personnel records revealed the following 6 testing personnel, their training dates, and documentation of the competency assessments performed: a) Testing person #1 i-STAT training: 4/2/19 Competency assessment: 11/7/19 and 8/13 /20 Based on the training date, testing person #1 should have had at least 2 competency assessments performed prior to 4/2020. b) Testing person #2 i-STAT training: 4/2/19 Competency assessment: 3/10/20 and 9/24/20 Based on the training date, testing person #2 should have had at least 2 competency assessments performed prior to 4/2020. c) Testing person #3 i-STAT training: 11/7/19 Competency assessment: 9/24/20 Based on the training date, testing person #3 should have had at least 2 competency assessments performed prior to 11/2020. d) Testing person #4 i-STAT training: 1/28/20 Competency assessment: 8/13/20 and 4/5/21 Based on the training date, testing person #4 should have had at least 2 competency assessments performed prior to 1/2021. e) Testing person #5 i-STAT training: 4/2/19 Competency assessment: 3/10/20 and 9/23/20 Based on the training date, testing person #5 should have had at least 2 competency assessments performed prior to 4/2020. f) Testing person #7 i-STAT training: 4/2/19 Competency assessment: 3/10/20 and 9/24/20 Based on the training date, testing person #7 should have had at least 2 competency assessments performed prior to 4/2020. 4. The laboratory director was asked to provide documentation of a second competency assessment being performed on the above testing personnel. No documentation was provided. 5. An interview with the laboratory director on 4/6/21 at 10:00 a.m. in the conference room, after review of the records, confirmed the above findings.