

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2010725	(X3) Date Survey Completed 10/12/2022
Name of Provider or Supplier Encompass Health Rehabilitation Hospital	Street Address, City, State 7930 Northaven Road, Dallas, 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	The laboratory was found out of compliance with the CLIA regulations. The condition not met was: D6063 - 42 C.F.R. 493.1421 Condition: Laboratories performing moderate complexity testing; testing personnel; Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representatives were given an opportunity to provide evidence of compliance with noted deficiencies and no such evidence was provided prior to survey exit.
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions for the Abbott i-STAT analyzer, and staff interview, it was revealed the laboratory failed to have documentation of ensuring test cartridges were received at an acceptable temperature. The findings include: 1. Base on review of the manufacturer's instructions for the Abbott i-STAT analyzer (REV. DATE: 15-Apr-2020) under the section titled "Check Temperature Monitor" revealed: "i-STAT cartridges are shipped refrigerated with a four-window indicator to monitor temperature during transit. Note: All control and calibration verification materials, except for those shipped on dry ice, will also include a four-window indicator to monitor temperature during transit. Action: If all windows are white or if only the A or B windows are blue or the 1 and 2 windows are red, then transit temperatures were satisfactory and the cartridges can be used. Remedial Action: If the C or D windows are blue, or the 3 and 4 windows are red: - quarantine the suspect cartons. - notify the i-STAT 1 System coordinator immediately - DO NOT</p>

	<p>USE cartridges from the suspect cartons." 2. The laboratory was asked to provide documentation of evaluating the four-window indicators which were received with each shipment for acceptable temperatures being maintained during shipment. No documentation was provided. 3. An interview with the technical consultant on 10/12/2022 at 1200 hours in the office revealed the laboratory did not evaluate the temperature of the cartridges upon arrival. This confirmed the findings.</p>
<p>D6046</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel records, and staff interview, it was revealed the facility failed to have documentation of the technical consultant performing competency assessments on 3 of 10 competency assessments performed in 2021 and 2022. The findings include: 1. A review of the laboratory's personnel files revealed 3 of 10 competency assessments performed in 2021 and 2022 were performed by someone other than the technical consultant. They were (as listed on Form CMS 209): Testing personnel number 1 annual competency performed April 2022 Testing personnel number 3 annual competency performed October 2022 Testing personnel number 4 semiannual competency performed April 2022 2. The laboratory was asked to provide documentation of the technical consultant performing the identified competency assessments. No documentation was provided. 3. An interview with the technical consultant on 10/12/2022 at 0940 hours in the office - after her review of the records- confirmed the findings.</p>
<p>D6053</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of the technical consultant perform two competency assessments within the first year for 1 of 3 testing personnel. The findings include: 1. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of the technical consultant performing two competency assessments within the first year for testing personnel number 3 (as listed on Form CMS 209). Hire date: July 2021 1st competency: December 2021 2nd competency: October 2022 2. The laboratory was asked to provide documentation of the technical consultant performing a second competency assessment by July 2022. No documentation was provided. 3. An interview with the technical consultant on 10/12/2022 at 0940 hours in the office - after her review of the records- confirmed the findings.</p>
<p>D6063</p>	<p>LABORATORY TESTING PERSONNEL</p>

CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:

Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of education to qualify 1 of 4 testing personnel (refer to D6065).

D6065

TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of education to qualify 1 of 4 testing personnel. The findings include: 1. A review of the laboratory's submitted Form CMS 209 revealed the facility identified 4 testing personnel. 2. A review of the laboratory's personnel records revealed the facility failed to have documentation of education to qualify 1 of 4 testing personnel. The person was (as listed on Form CMS 209): Testing personnel number 2 3. The laboratory was asked to provide documentation of education to qualify testing personnel number 2. No documentation was provided. 4. An interview with the technical consultant on 10/12/2022 at 0940 hours in the office - after her review of the records- confirmed the findings.