

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2117237	(X3) Date Survey Completed 01/13/2021
Name of Provider or Supplier Lakeway Complete Care Llc	Street Address, City, State 1518 Ranch Road 620 South,Suite 200, Lakeway, 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
D2089	<p>ROUTINE CHEMISTRY CFR(s): 493.841(c)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the the CMS-155 individual Profile report, the American Proficiency Institute (API) proficiency testing records for 2019 and 2020, Quality control records, patient test records and interview of facility personnel, the laboratory failed to participate in 2 of three consecutive testing events (3 events annually) for the analytes Lactic Acid, Magnesium and Phosphorous. The findings included: 1. Review of the Casper 155 individual proficiency testing report found: a. The laboratory received a score of 0% for 16 of 16 analytes Albumin, BNP, Calcium, Chloride, CO2, Creatine Kinase Isoenzyme, Creatinine, D-dimer Glucose, Lactic Acid, Magnesium, Phosphorus, Potassium, Sodium, Troponin I and Urea Nitrogen in the 2019 Chemistry Core 3rd event. b. The laboratory received a score of 100% for 15 of 16 analytes (80% for Creatine Kinase Isoenzyme in the 2020 Chemistry Core 2nd Testing event. 2. Based on review of the (API) proficiency testing records found: a. The laboratory failed to test and submit results for the 2019 Chemistry Core 3rd testing event to the proficiency testing agency for grading prior to the final submission date of September 13, 2019 resulting in an unacceptable score of 0% for 16 of 16 analytes. Further</p>

review found the laboratory failed to test proficiency specimens CH 11- CH15 until September 16, 2019 and performed a self evaluation of the results obtained on November 6, 2019. b. Review of the 2020 Chemistry Core 2nd testing event, found: I. The laboratory tested proficiency specimens CH06, CH 07 and CH10 on May 26, 2020 using the CMP discs and the Liver panel discs. Specimen CH09 was tested on May 27, 2020 using the CMP discs and the Liver panel discs. Specimen CH08 was tested May 28, 2020 using the CMP discs and the Liver panel discs. The laboratory reported a test problem for specimens CH06 - CH10 (five specimens) for the analytes Lactic Acid, Magnesium, and Phosphorus and submitted the results to the proficiency testing agency on June 9, 2020 at 5:16 PM. c. Review of the Comparative Evaluation for the 2020 Chemistry Core 2nd Testing event found the laboratory received a score of 100% for 15 of 16 analytes (80% for Creatine Kinase Isoenzyme). 3. Review of the Met Lac 12 quality control records found that the laboratory tested quality control specimens using Met Lac 12 lot 9463BC2 on February 22, 2020, with the next quality control procedures performed on May 29, 2020 using Met Lac 12 Panel lot 0185AC1. Documentation found the Met Lac 12 panels were on back order after January 1, 2020. 4. Review of patient test records found the laboratory tested 3 patient specimens using the Met Lac 12 discs between May 29, 2020 (date of receipt) and June 9, 2020 (date of proficiency testing results submission). 5. Interview of the Technical Consultant conducted on January 13, 2021 at 10:42 AM confirmed the laboratory failed to test the 2019 Chemistry Core proficiency testing specimens for the 3rd testing event prior to the final submission date. She also stated that the laboratory was notified in January 2020 that Met Lac 12 panels were on back order. The laboratory had no Met Lac 12 disks (for use on the Abaxis Piccolo analyzer) on May 26, 2020 to test the five specimens received in the 2020 2nd Chemistry Core testing event, so testing personnel used the CMP and Liver Panel discs to complete as many of the analytes that were to be reported. She stated that the Panels were received and quality control procedures were performed on May 29, 2020. She stated she suggested to the laboratory to test the proficiency specimens on the correct discs to report to the proficiency testing agency, but the lab did not want to repeat the testing. They were able to complete testing for all analytes except the Lactic Acid, Magnesium and Phosphorous. They reported an instrument problem to API that they did not have the discs to perform these tests.

D6016

LABORATORY DIRECTOR RESPONSIBILITIES
 CFR(s): 493.1407(e)(4)(i)

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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:
 Based on review of the laboratory's proficiency testing records for 2019 and 2020, the CMS-155 proficiency testing report, and confirmed in staff interview, the laboratory director failed to ensure proficiency testing samples were tested as required to achieve successful scores.(Refer to D 2089)

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 proficiency testing records from 2019 and 2020 and staff interview the laboratory director failed to ensure proficiency test results were returned prior to the submission deadline in one of six Chemistry testing events. (refer to D2089).