

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2110360	(X3) Date Survey Completed 02/05/2020
Name of Provider or Supplier Westlake Complete Care Llc	Street Address, City, State 6836 Bee Caves Rd Suite 112, Austin, 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 surveyed and failed to meet the following conditions of the CLIA regulations found at CFR 42 493.1 through 493.1780: 493.1403 Condition: Laboratories Performing Moderate Complexity Testing; Laboratory Director 493.1421 Condition: Laboratories Performing Moderate Complexity Testing; Testing Personnel
D6000	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on review of laboratory policies and procedures, quality control records, patient test records, and confirmed in interview with laboratory staff, the Laboratory Director failed to provide overall management and direction to the laboratory. 6. The laboratory Director failed to ensure that Testing personnel had received the appropriate education and training prior to performing non waived testing. (See D 6028 and D6029)</p>
D6028	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(10)</p> <p>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)(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate</p>

consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart;

This STANDARD is not met as evidenced by:
Review of personnel files, laboratory test records, patient test records and interview of facility personnel found that the laboratory director failed to ensure that two of 15 testing personnel performing non waived testing had the appropriate education and training for performing non waived procedures. (see D 6065 and D6066)

D6063

LABORATORY TESTING PERSONNEL
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:
Review of the CMS Report 209 Laboratory Personnel Report, personnel records and interview of facility personnel found that two of 15 testing personnel failed to meet the minimum requirements for performing moderate complexity testing. (See D6065, D6066)

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:
Review of the CMS 209 Laboratory Personnel Report, Personnel records, patient test records and interview of facility personnel found that the laboratory failed to ensure that one of 15 testing personnel listed on the CMS Report 209 performing moderately complex testing held the minimum education requirements of a high school diploma or general education diploma (GED). Findings included: 1. Review of personnel records found testing person 15 (hired February 2018) had no foreign equivalency evaluation for education received in Canada available for review 2. review of patient test records between February 9, 2018 and February 4, 2020 found testing person 15 had tested: 19 patient samples for Complete Blood counts (CBC) using the Horiba micros 60 5 patient samples using the Met Lac 12 panel on the Abaxis Piccolo 2 patient samples using the Cardiac Marker panel of the Alere Triage meter 2 patient samples using the D dimer on the Alere triage meter. 3. Interview of technical

consultant 2 listed on the CMS Report 209 Laboratory Personnel report conducted on February 4, 2020 at 10:45 AM confirmed that education records had not been evaluated by the world credentialing evaluations services. She went on to say that testing person 15 tested patient specimens until she discovered the high school diploma was from a a High school in Canada.

D6066

TESTING PERSONNEL QUALIFICATIONS
CFR(s): 493.1423(b)(4)(ii)

Have documentation of training appropriate for the testing performed prior to analyzing patient specimens.

This STANDARD is not met as evidenced by:
Review of the CMS 209 Laboratory Personnel Report, Personnel records, patient test records and interview of facility personnel found that the laboratory failed to ensure that one of 15 testing personnel listed on the CMS Report 209 performing moderately complex testing had received training for moderately complex testing at this facility before testing patient specimens . Findings included: 1. Review of personnel records found testing person 12 (hired August 2019) had no documentation of training at this laboratory available for review. 2. review of patient test records between August 2019 and February 5 2020 found testing person 2 had not tested any patient specimens for moderately complex procedures. 3. Interview of technical consultant 2 listed on the CMS Report 209 Laboratory Personnel report conducted on February 4, 2020 at 10:45 AM confirmed that training records offered for review were from another laboratory in San Antonio.