Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2110360	02/14/2018
Name of Provider or Supplier	**Street Address, City, State**	
Westlake Complete Care Llc	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
D2005	ENROLLMENT CFR(s): 493.801(a)(4) Authorize the proficiency testing program to release to HHS all data required to-- (i) Determine the laboratory's compliance with this subpart; and (ii) Make PT results available to the public as required in section 353(f)(3)(F) of the Public Health Service Act. This STANDARD is not met as evidenced by: Based on review of the CMS 155D proficiency testing report, review of the laboratory's American Proficiency Institute's (API) proficiency testing records from 2017, and staff interview, the laboratory failed to ensure proficiency testing data was released to HHS for 3 of 3 events in 2017. The findings were: 1. Based on a review of the laboratory's CMS 155 proficiency testing report, proficiency testing data was not being sent to HHS for the following regulated analytes found in 42 CFR part 493 subpart I: Albumin Blood urea nitrogen Calcium Chloride Creatinine Glucose Potassium Magnesium Sodium 2. At 11:09 hours on 2/14/2018, the surveyor called the Abaxis technical support number listed on the MetLac 12 Panel instructions for use (part number 400-7192-1, Rev. G). The Abaxis technical representative provided two documents from Abaxis that list the MetLac 12 Panel reagent cartridge as moderate complexity (product information sheets 888-3210 and piccolo 888-3010). 3. Based on a review of the laboratory's American Proficiency Institute's proficiency testing records from 2017 (events 1, 2, and 3), the proficiency testing agency was not sending data to HHS. The laboratory was enrolled in proficiency testing for the regulated analytes listed above; however, the laboratory had previously reported the analytes as waived complexity. Based on a review of the American Proficiency Institute's proficiency testing instructions, under "Reporting Instructions:", number 8 states "Abaxis Piccolo or Alere Cholestech users need to choose either waived reagent or moderately complex reagent. If you are using serum to perform patient testing, your method is considered moderately complex. You must test five samples in order

	to be in compliance with CLIA, and your proficiency results will be sent to CMS. If you are using whole blood to perform testing, your method is considered waived. Your proficiency scores will not be sent to CMS." 4. In an interview at 11:15 hours on 2/14/2018, the Technical Consultant stated the laboratory routinely tests whole blood specimens and had followed the American Proficiency Institute's proficiency testing instructions for reporting proficiency results.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of proficiency testing records and interview with facility personnel, the laboratory failed to assess the accuracy twice annually (2 of 2) for the analytes Lactate and Phosphorus for the year 2017. The findings included: 1. Based on review of Food and Drug Administration (FDA) decision summary K130113, the analyte Lactate is moderate complexity on the reagent cartridge MetLac 12 for the Abaxis Piccolo xpress chemistry analyzer. The Lactate analyte is not a regulated analyte found in 42 CFR part 493 subpart I and is subject to twice annual accuracy verification. At 11:09 hours on 2/14/2018, the surveyor called the Abaxis technical support number listed on the MetLac 12 Panel instructions for use (part number 400-7192-1, Rev. G). The Abaxis technical representative provided two documents from Abaxis that list the MetLac 12 Panel reagent cartridge as moderate complexity (product information sheets 888-3210 and piccolo 888-3010). The analyte Phosphorus is not a regulated analyte found in 42 CFR part 493 subpart I and is subject to twice annual accuracy verification. 2. Based on review of American Proficiency Institute (API) proficiency testing records, the laboratory did not submit Lactate or Phosphorus results on proficiency testing challenges to be graded. The laboratory did not perform another method of accuracy assessment for the analytes Lactate and Phosphorus at least twice annually for 2017. 3. In an interview at 11:42 hours in the breakroom, the Technical Consultant stated the laboratory had tested Lactate and Phosphorus on the proficiency testing samples but did not submit the scores for evaluation or perform another means of accuracy assessment.
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 review of the laboratory's Individualized Quality Control Plan (IQCP) procedure and interview with facility personnel, the laboratory failed to identify the

	frequency and potential impact for each potential source of error identified in the laboratory's Risk Assessment (RA) for the Abaxis Piccolo xpress chemistry analyzer. The findings included: 1. Based on review of Food and Drug Administration (FDA) decision summary K130113, the analyte Lactate is moderate complexity on the reagent cartridge MetLac 12 for the Abaxis Piccolo xpress chemistry analyzer. 2. Review of the Risk Assessment portion of the IQCP for the Abaxis Piccolo xpress chemistry analyzer test system, signed by the laboratory director on 10/19/2016, included potential sources of error for the following categories: Specimen, Reagent, Test System, Environment, and Testing Personnel. The Risk Assessment DID NOT include the frequency with which the laboratory defined potential sources of error had occurred or were likely to occur. As a potential risk, the laboratory identified "incorrect results due to operation the measuring system outside of the manufacturer's environmental specifications." The lab did not define how often (frequency) the risk was likely to occur or the impact (risk to the patient) if the instrument were operated outside of the defined requirements. 3. The Risk Assessment DID NOT include an assessment of the potential impact on patient results for each laboratory defined potential source of error. The lab defined "Incorrect results due to low-volume sample" as a potential risk of error. The laboratory did not define how often (frequency) that specimens were rejected due to not meeting the volume requirements for testing or the impact (risk to patient) if low-volume specimens were tested, instead. 4. In an interview at 13:25 hours on 02/14/2018 in the breakroom, the Technical Consultant stated that the laboratory monitored potential sources of error through quality assurance activities but had not defined the frequency and impact of each source of error as part of the IQCP risk assessment.