Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2167678	01/17/2020
Name of Provider or Supplier	**Street Address, City, State**	
Lakewood Ccl, Llc	5571 E Sr 44 Suite 502, Wildwood, FL	

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	An announced CLIA initial survey was conducted at Lakewood CCL, LLC on 01/15 /2020 - 01/17/2020. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following is a description of the standard level deficiencies:
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on record review of the procedure manual and the validation of the Activated Clotting Time (ACT) test, and interview with the Technical Consultant #D, the laboratory failed to complete the performance verification for the ACT on the iStat instrument prior to patient testing. Findings included: Record review of the laboratory's procedure manual showed a procedure titled "Evaluation of Test Methods" and the procedure included this statement "The laboratory will verify the following manufacturer's stated performance specifications provided in the package insert before reporting patient results: Precision, Accuracy, Reportable Range (Linearity studies), Reference Range, and Method Comparison (if required by your state regulatory agency and/or to compare the new method with the method presently in use in the laboratory)". Record review of the performance verification performed 09 /16/19 - 11/21/19 for the ACT test performed on the iStat instrument revealed that precision and accuracy studies had been performed but there were no records

	available for review that showed that the laboratory had verified the manufacturer's reportable range. The manufacturer's reportable range for the ACT test is 50-1000 seconds. Review of the Patient's ACT result log revealed 2 patients (10/7/19 and 10 /24/19) were reported during the precision and accuracy performance verification studies and 1 patient was reported 01/13/20. On 10/7/2019 ACT level 1 and level 2 controls had been tested 7 times for precision and accuracy studies and on 10/24/19 the ACT controls had been tested 12 times. Phone interview on 01/16/2020 at 3:00 PM with Technical Consultant #D revealed he was informed by Testing Personnel #B that the heparin study (linearity study) was done during the training of testing personnel. Technical Consultant #D stated he would try to obtain these documents. On 01/17/2020, Technical Consultant #D sent electronic correspondence stating the heparin study had not been performed.
D6005	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(c) 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. (c) The laboratory director must be accessible to the laboratory to provide onsite, telephone or electronic consultation as needed. This STANDARD is not met as evidenced by: Based on record review of the laboratory's Internal Quality Control Program (IQCP) and interview with Technical Consultant #D, the laboratory failed to have a written delegation for the Technical Consultant #D to perform the task of development and implementation of the IQCP that was signed 11/22/19 by the Laboratory Director. Findings included: Review of the IQCP revealed the IQCP had been developed and implemented by Technical Consultant #D, but the Laboratory Director had not provided a written delegation for this task to Technical Consultant #D. Phone interview on 01/16/2020 at 3:05 PM with Technical Consultant #D confirmed that he had developed and implemented the IQCP with no written delegation from the Laboratory Director.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (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. This STANDARD is not met as evidenced by: Based on record review and interview with Testing Personnel #B, the Technical Consultant #D failed to perform Activated Clotting Time (ACT) initial competency evaluations on 4 (#C, #F, #G, and #H) of 6 Testing Personnel (#B, #C, #E, #F, #G, and #H). Findings Included: Review of the job description signed 09/18/19 for the Technical Consultant #D revealed the Technical Consultant was responsible for evaluating the competency of all testing personnel on an on-going basis. Review of employee competencies revealed the 09/16/2019 ACT Initial Competency for Testing Personnel #C was performed by Testing Personnel #E, the 01/13/20 ACT Initial

	Competency for Testing Personnel #G and #H were performed by Testing Personnel #E, and the 01/13/20 ACT Initial Competency for Testing Personnel #F was performed by Testing Personnel #B. Interview on 01/15/2020 at 11:15 AM with Testing Personnel #B revealed that Technical Consultant #D delegated her and Testing Personnel #E to perform initial competencies, but this was not done in writing. Review of the personnel record for Testing Personnel #B and #E revealed the highest level of education completed for Testing Personnel #E was a high school diploma and Testing Personnel #E was an Associates of Science in Nursing.