

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 42D2241290	(X3) Date Survey Completed 06/27/2024
Name of Provider or Supplier Lakelands Family Practice & Pediatric Center	Street Address, City, State 17124 Highway 72 West, Waterloo, SC	
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 Lakelands Family Practice and Pediatric Center on 06/27/2024 by the South Carolina Department of Environmental Control (SCDHEC). The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. The facility was found to be out of compliance with the standards of the CLIA program. The following STANDARD LEVEL DEFICIENCIES were found to be out of compliance:
D5409	<p>PROCEDURE MANUAL CFR(s): 493.1251(e)</p> <p>The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2).</p> <p>This STANDARD is not met as evidenced by: During an onsite survey on 06/27/2024 procedures reviewed, records reviewed, and staff interviewed the laboratory failed to maintain a copy of each procedure with the dates of initial use and discontinuance. 2022 to 2024 two years reviewed. Findings included: 1. A written procedure titled Urinalysis with microscopics outlined how to perform an analysis on urine. 2. Review of proficiency testing records from American Proficiency Institute (API) revealed that hematology specialty was performed. No urinalysis proficiency testing documented. 3. During an interview with technical consultant on 06/27/2024 at 3:10 pm, it was confirmed that microscopic examination is not performed at Lakelands Family Practice & Pediatric Center.</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's</p>

instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:
Based on direct observation, manufacturer's label instructions, record review and staff interview the laboratory failed to follow manufacturer's instructions for acceptable room temperature range. Findings included: 1. During a tour of the laboratory on 06/27/2024 at 12:49 pm, the surveyor observed the following blood collection tubes in the laboratory. a. 5 packs of Becton Dickinson (BD) Tiger Top tubes, Lot #4081991, expires 02/28/2025 b. 2 packs of BD Tiger Top tubes, Lot #4022609, expires 12/31/2031 c. pack of BD Tiger Top tubes, Lot #3347114, expires 12/31/2024 d. 2 packs of BD Purple Top tubes, Lot#3314540, expires 02/28/2025 e. 2 packs of BD Purple Top tubes, Lot#4073992, expires 07/31/2025 f. 1 pack of BD Purple Top tubes, Lot#3163674, expires 10/31/2024 2. A review of the manufacturer's instructions labeled on the pack of the BD blood collection tubes revealed a room temperature requirement of 4-25C/39.2-77F. 3. Review of random laboratory environmental records 2023 revealed the laboratory's acceptable room temperature range of 68-90F/20-32C. The laboratory acceptable room temperature range exceeded the upper limit of 25C for the blood collection tubes. Key Celsius = C Fahrenheit = F

D5415

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(c)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:
Based on direct observations, and staff interview the laboratory failed to label complete blood count (CBC) controls with open and expiration dates for 2 out of 3 tubes. Findings included: 1. During a tour of the laboratory on 06/27/2024 at 12:49pm with technical consultant, the surveyor directly observed the following quality controls: a. Abbott, Cell-Dyn 18 Plus Control H, Lot#4092, expires 07/19/2024 b. Abbott, Cell-Dyn 18 Plus Control L, Lot#4092, expires 07/19/2024 No documentation of open and or expiration dates written on bottle. 2. A review of Assay Sheet for Cell-Dyn 18 Plus Controls, revealed quality controls expire within "8 consecutive-Day Open-Tube Stability". 3. In an interview with on 06/27/2024 at 12:49 pm in the laboratory with technical consultant the above findings were confirmed.

D5429

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:
Based on instrument operator 's manual, records review, and staff interview the laboratory failed to perform and document maintenance as defined by the manufacturer. 29 out of 29 months reviewed lack documentation. Findings included:
1. Review of Cell-Dyn Emerald Quick Reference Card under "Daily Start Up" #6. Check the instrument maintenance log and perform any required maintenance. 2. Review of the laboratory's maintenance log of Cell-Dyn Emerald Operator's Manual, 9213301B-October-2018 log sheets revealed lack of documentation for semi-annual maintenance from January 2022 through May of 2024. 3. In an interview on 06/27 /2024 at 3:10pm with technical consultant the above findings were confirmed.

D5783

CORRECTIVE ACTIONS
CFR(s): 493.1282(b)(2)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:
Based on records reviewed and staff interviewed the laboratory failed to document all corrective actions when results failed to fall within the defined limits of acceptability. 24 months (2022 to 2024) reviewed. Findings included: 1. Review of quality control reports for Cell-Dyn 18 Plus Controls used with Abbott Cell-Dyn Emerald instrument. 2. Random months selected from 2022 to 2024 revealed the following results: September 22, 2022, Normal level, Lot #N2234 a. White Blood Cells (WBC) resulted 2.3, acceptable expected value 7.1 to 9.1 b. Lymphocytes (Lym)% resulted 51.8, acceptable expected value 17.5 to 35.5 c. Granulocytes% resulted 43.3, acceptable expected value 58.9 to 76.9 d. MID (cells less frequently occurring and rare cells correlating to monocytes, eosinophils, basophils, blasts and other precursor white cells) resulted 0.1, acceptable expected value 0.2 to 0.8 e. Granulocytes (neutrophils, eosinophils, and basophils) resulted 1.0, acceptable expected value 3.5 to 7.5 f. Red Blood Cells (RBC) resulted 2.26, acceptable expected value 3.89 to 4.39 g. Hemoglobin (HGB) resulted 5.1, acceptable expected value 10.2 to 11.6 h. Hematocrit (HCT) resulted 17.2, acceptable expected value 30.9 to 37.9 i. Mean Corpuscular Volume (MCV) resulted 76.1, acceptable expected value 78 to 88 j. Mean Corpuscular Hemoglobin (MCH) resulted 22.6, acceptable expected value between 23.8 to 28.8 k. Platelets (PLT) resulted 69, acceptable expected value between 171 to 241 b. No corrective action log for quality control failures, or any laboratory incidents showing investigation and/or actions taken to prevent future occurrences. 3. An interview on 06/27/2024 at 3:10 pm with technical consultant and the above findings were confirmed.