

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 42D0251789	(X3) Date Survey Completed 06/24/2024
Name of Provider or Supplier McLeod Dillon Family Medicine	Street Address, City, State 603 North Sixth Avenue, Dillon, 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 on-site announced CLIA initial survey was conducted at McLeod Dillon Family Medicine's clinical laboratory on June 24, 2024 by the South Carolina Department of Health and Environmental Control's (SC DHEC) Bureau of Healthcare Systems and Services. The laboratory was found to be out of compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the STANDARD level deficiencies:
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation, records review, and staff interview, 1 of 24 attestation statements reviewed for 3 of 3 years was not signed by the testing personnel (TP) and the laboratory director (LD). Findings included: 1. An attestation statement document dated May 24, 2022, lacks the signatures of 5 testing personnel and the laboratory director. 2. In an interview with the general supervisor (GS) and the LD on June 24, 2024 at 4:45pm in the laboratory conference room, the finding was confirmed.</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 instructions, if provided. These conditions must be monitored and documented and, if</p>

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 instructions, laboratory environmental records, and staff interview, the laboratory failed to use appropriate range for room temperature for the storage of blood collection tubes. Findings included: 1. During the laboratory tour on June 24, 2024, at 3:00pm with TP4 revealed the following: a. 2 packs of vacuette, expiration date 04/01/2025, lot # B240133 b. 3 packs of tiger top Becton Dickenson (BD) vacutainer tubes, expiration date 02/28/2025, lot # 4068649. c. 2 packs of lavender top BD vacutainer tubes, expiration date 02/28/2025 lot # 4045194. 2. All of the above packs have a manufacturer's recommended storage temperature of 4-25 degrees celcius (C)(39.7-77 degrees fahrenheit) (F). 3. A review of environmental log records reveal 64 to 86 degrees F as an unacceptable range for room temperature. 4. In an interview with the TP6 on June 24, 2024 in the laboratory conference room at 3:00 pm, confirmed that the laboratory was using 64-86 degrees F as their acceptable room temperature.

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 document review, direct observation, and staff interview, the laboratory failed to properly label opened quality control materials with opening and expiration dates in 3 out of 6 bottles observed. Findings included: 1. BioRad unassayed multiquality quality control materials included: a. Level 1 lot # 56741, expiration date 08/31/2026 b. Level 2 lot # 56742, expiration date 08/31/2026 c. Level 3 lot # 56743, expiration date 08/31/2026 2. During a tour of the laboratory on June 24, 2024 at 2:45 pm, the surveyor observed current quality control bottles that lacked documentation of opened and expiration dates. 2. In an interview with TP4 on June 24, 2024, at 2:27 pm in the laboratory, the findings were confirmed.

D6036

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413

The technical consultant is responsible for the technical and scientific oversight of the laboratory.

This STANDARD is not met as evidenced by:

Based on document review, review of employee competency evaluations, and staff interview, the laboratory failed to ensure the technical consultant (TC) performed oversight of the laboratory in 20 out of 20 competencies reviewed. Findings included: 1. Review of the CMS-209 form reveals the LD serving as the TC. 2. Review of

personnel records in 3 out of 3 years reviewed were not signed off by the TC. 3. In an interview on June 24, 2024, at 3:00pm in the laboratory conference room with the LD and TP4, confirmed that the LD was not serving as the TC for personnel competency evaluations. 4. Review of personnel records revealed TP4 lacks qualification documentation for the TC position in a moderate complexity laboratory.