

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 42D0249617	(X3) Date Survey Completed 02/06/2024
Name of Provider or Supplier Doctor's Care - Shandon	Street Address, City, State 2601 Rosewood Drive, Columbia, 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 recertification survey was conducted at Doctor's Care-Shandon on 02/06/2024 by the South Carolina Department of Environmental Control (SCDHEC). The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. Specific standard level deficiencies cited are as follows:
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation, manufacturer's instructions, laboratory environmental records, and in staff interview, the laboratory failed to ensure the proper storage conditions of 4 of 4 COVID 19 kits and 11 of 11 Abbott Influenza kits were maintained according to manufacturer's instructions. Findings included: 1. During a tour of the laboratory on 02/06/2024 at 4:12pm, the surveyor observed the following waived test kits in a storage room next to the laboratory: a. 4 boxes COVID 19 Kits, Lot # M819642, b. 11 boxes Abott Influenza A&B 2 ID Now Kits, Lot # M785486 There was no thermometer observed in the storage room on 02/06/2024 at 4:12pm to monitor room temperature. 2. Manufacturer instructions for the Covid and Influenza test kits stated a storage temperature of 2 to 30C/35.6 to 86F. 3. Review of the laboratory's environmental records revealed no documentation of room temperature monitoring of the storage room. The laboratory was asked to provide documentation, and none was provided. 4. During an interview on 02/06/2024 at 4:14 pm, the Clinic Manager confirmed that room temperature was not monitored or documented for the storage room. Word Key: C=Celsius F=Fahrenheit</p>
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES

CFR(s): 493.1235

As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

This STANDARD is not met as evidenced by:

Based on review of the Center for Medicare and Medicaid (CMS) 209 form, laboratory policies, personnel records, and confirmed in staff interview, the laboratory failed to establish and follow a policy to assess responsibilities for one of one technical consultant. Findings included: 1. The laboratory's submitted CMS-209 form listed one Technical Consultant (TC-1). 2. Review of the laboratory's policies revealed the laboratory failed to establish a competency assessment policy for the TC-1 responsibilities. 3. Review of the laboratory's personnel records revealed no documentation of competency assessment for the TC. 4. In an interview on 02/06/2024 at 11:30am in the breakroom, the clinic manager was asked to provide documentation of competency assessment for the TC. No documentation was provided. She stated that the laboratory did not have a policy for TC-1 competency assessment.

D5411

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

Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

This STANDARD is not met as evidenced by:

Based on review of the Boule hematology controls manufacturer's instructions, laboratory procedure, and confirmed in staff interview, the laboratory failed to follow manufacturer's instructions for handling quality control material. Findings included: 1. Boule Con-Diff Tri-Level manufacturer's instructions stated in the section titled "Instructions for Use", "2. Mix by hand as follows: a. Roll the tube or vial slowly between the palms of the hands 15-20 seconds in an upright position. b. Invert the tube and slowly roll it back and forth for another 15-20 seconds." 2. The Medonic M-Series Hematology analyzer procedure manual stated in the section "Instructions for Use", "2. After warming, mix by hand as follows: a. Roll the tube or vial slowly between the palms of the hands eight times in the upright position. b. Invert the tube slowly roll it between the palms eight times." The laboratory procedure failed to follow the quality control material manufacturer's instructions. 3. In an interview on 02/06/2024 at 10:50am in the laboratory, the clinic manager confirmed the laboratory was not following the manufacturer's instructions for mixing the quality control specimens.

D5413

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

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 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:

I. Based on review of direct observation, review of manufacturer's instructions, laboratory procedure, laboratory environmental logs (May-August 2023), and confirmed in staff interview, the laboratory failed to establish an acceptable room temperature range for four (4) of four (4) months. Findings included: 1. During a tour of the laboratory on 02/06/2024 at 4:12pm, the surveyor observed the following in the laboratory area: a. Medonic M-series Hematology analyzer b. Becton Dickinson (BD) Plain Red top glass blood collection tubes, Lot # 2166007, 7 packages c. BD Purple top blood collection tubes, Lot # B23043HQ, 6 packages d. BD Tiger top blood collection tubes, Lot # 3283911, 1.5 packages 2. A review of the manufacturer's instructions labeled on the box of the BD blood collection tubes revealed a room temperature requirement of 4-25C/39.2-77F. 3. The laboratory procedure (SOP 6.001.1) titled; "Medonic M-Series Hematology Analyzer" stated "room temperature is between 18 to 32C." 4. Review of the laboratory's environmental logs (May - August 2023) revealed the laboratory's acceptable room temperature range of 65-90F /18-32C: The laboratory's acceptable room temperature range exceeded the upper limit of 25C for the blood collection tubes. 5. During an interview on 02/06/2024 at 4:14 pm, the Clinic Manager confirmed the laboratory's room temperature range was not acceptable for the laboratory area. II. Based on review of the laboratory policy, laboratory environmental logs (May-August 2023), and confirmed in staff interview, the laboratory failed to ensure that the room temperatures for the laboratory were within acceptable range for 18 of 123 days. Findings included: 1. The laboratory procedure (SOP 6.001.1) titled; "Medonic M-Series Hematology Analyzer" stated "room temperature is between 18 to 32C." 2. A review of laboratory monthly temperature and humidity quality control logs revealed 18 out of 123 days room temperatures for the laboratory area were out of acceptable range (18-32C/64.4-89.6F) as documented on log: a. May 18, 2023 Temperature 51.2F Outside of acceptable limit= 13.2 degrees b. June 21, 2023 Temperature 62.4F Outside of acceptable limit= 2 degrees c. June 24, 2023 Temperature 63.4F Outside of acceptable limit=1 degrees d. June 27, 2023 Temperature 62.4F Outside of acceptable limit=2 degrees e. July 4, 2023 Temperature 63.2F Outside of acceptable limit=1.2 degrees f. July 7, 2023 Temperature 63.5F Outside of acceptable limit=0.9 degrees g. July 21, 2023 Temperature 61.7F Outside of acceptable limit=2.7 degrees h. July 31, 2023 Temperature 62.4F Outside of acceptable limit= 2 degrees i. August 5, 2023 Temperature 64.2F Outside of acceptable limit=0.2 degrees j. August 9, 2023 Temperature 62.7F Outside of acceptable limit= 1.7 degrees k. August 17, 2023 Temperature 63.9F Outside of acceptable limit=0.5 degrees l. August 20, 2023 Temperature 63F Outside of acceptable limit=1.4 degrees m. August 21, 2023 Temperature 63F Outside of acceptable limit=1.4 degrees n. August 22, 2023 Temperature 63F Outside of acceptable limit=1.4 degrees o. August 24, 2023 Temperature 61.2F Outside of acceptable limit=3.2 degrees p. August 25, 2023 Temperature 61.6F Outside of acceptable limit=2.8 degrees q. August 27, 2023 Temperature 61.3F Outside of acceptable limit=3.1 degrees r. August 30, 2023 Temperature 61.1F Outside of acceptable limit=3.3 degrees 3. In an interview on 2/06/2024 at 4:14pm, the clinic manager confirmed the laboratory failed to recognize temperatures outside of the acceptable range.

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 review of the Medonic M-Series operator's manual, laboratory policy, laboratory maintenance records (January 2023-January 2024), and confirmed staff interview, the laboratory failed to ensure that the monthly maintenance was performed for 2 of 13 months. Findings included: 1. A review of the operator's manual titled, "Medonic M-series User's Manual" revealed in section 8: cleaning, maintenance & transport, 8.2 monthly cleaning, pg. 65 monthly " ...cleaning is required for the correct function of the instrument ..." 2. A review of laboratory policy (SOP 6.001.1) titled, "Medonic M-Series Hematology Analyzer" stated, "instrument maintenance is performed monthly and semi-annually according to manufacturer's instructions, utilizing the Boule Cleaning kit." 3. Review of the laboratory maintenance records from January 2022 to January 2024 revealed the laboratory failed to document monthly maintenance for the following months: July 2023 January 2024 4. In an interview on 02/06/2024 at 4:12pm in the breakroom, the clinic manager was asked to provide documentation of monthly maintenance for July 2023 and January 2024. No documentation was provided. This confirmed the findings.

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:

Based on review of the submitted Centers for Medicare and Medicaid (CMS) 209 form, laboratory personnel records (2022 and 2023), and confirmed in staff interview, the TC failed to evaluate the annual competency of 5 of 5 testing personnel. Findings included: 1. Review of the documentation located on the CMS-209 form revealed one technical consultant (TC-1). 2. A review of the laboratory 's competency records revealed the following: a. Position: Testing Person (TP) 1 Date of competency: 06/21 /2023 Assessor: TP 6 b. Position: TP 2 Date of competency: 06/08/2023 Assessor: TP 1 c. Position: TP 3 Date of competency: 07/08/2023 Assessor: TP 1 d. Position: TP 4 Date of competency: 04/06/2023 Assessor: TP 1 e. Position: TP 5 Date of competency: No records provided. Assessor: No records provided 3. Review of the laboratory's personnel records revealed the testing person (TP-1) that performed the competency assessment did not qualify as technical consultant (TC). 4. In an interview 02/06/2024 at 4:14 pm in the breakroom, the clinical manager confirmed the findings.