Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	42D2042041	02/07/2024
Name of Provider or Supplier	**Street Address, City, State**	
Doctors Care City Of Columbia	2012 Harden St, Suite112, 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	A Recertification Survey was conducted at Doctors Care, City of Columbia on 02/07/2024. The laboratory was found not to be in substantial compliance with CLIA regulations 42 CFR Part 493. Standard level deficiencies were cited.
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 Centers 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). 2. Review of the laboratory's policies revealed the laboratory failed to establish a competency assessment policy for the technical consultant's responsibilities. 3. Review of the laboratory's personnel records revealed no documentation of competency assessment for the technical consultant. 4. In an interview on 02/07/2024 at 11:50am in the laboratory office, the clinic manager was asked to provide documentation of competency assessment for the technical consultant. No documentation was provided. She further stated that the laboratory did not have a policy for TC competency assessment.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling,

	storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on a review of laboratory policy, laboratory quality control records (October 2023), and confirmed in staff interview, the laboratory failed to follow its own quality control policy for repeating out of range control material for one (1) of 30 days. Findings included: 1. Review of the laboratory's policy manual for the Medonic M-Series Hematology analyzer stated, "if two or more controls are out of range, repeat the controls no more than one time each to see if the issue can be resolved." 2. Review of the quality control records for October 2023 revealed level 1 quality control (QC) was run 6 times on 10/06/2023 with no corrective action documented. Documentation as follows: a. Date: 10/06/2023 Time: 6:46 am Identification: 2230801 b. Date: 10/06 /2023 Time: 6:48 am Identification: 2230801 c. Date: 10/06/2023 Time: 6:51 am Identification: 2230801 d. Date: 10/06/2023 Time: 6:52 am Identification: 2230801 e. Date: 10/06/2023 Time: 6:54 am Identification: 2230801 f. Date: 10/06/2023 Time: 6: 56 am Identification: 2230801 3. In an interview on 02/07/2024 at 11:45 am in the laboratory office, the clinic manager was asked to provide documentation of corrective action for the out-of-range controls. No documentation was provided. The clinic manager confirmed that the laboratory failed to follow the quality control policy.
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 instructions for use, laboratory procedure, and confirmed in staff interview, the laboratory failed to follow manufacturer's instructions for the performance of quality control specimens. Findings included: 1. Boule Con-Diff Tri-Level package insert 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 slowly 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 an 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 02/07/2024 at 11:50 am in the laboratory office, 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 direct observation, review of the laboratory's environmental logs (2022 and 2023), and confirmed in staff interview, the laboratory failed to monitor room temperature in the laboratory storage closet for 24 of 24 months. Findings included: 1. During a tour of the laboratory storage closet on 02/07/2024 at 11:40 am, no thermometer was observed in use in the laboratory storage closet to ensure specified temperature requirements for the stored supplies. a. Supply: Becton Dickinson (BD) Vacutainer Type: K2 Ethylenediaminetetraacetic acid (EDTA) Quantity: 6.5 packages Lot: 2321358 b. Supply: BD Vacutainer Type: Serum (tiger top) Quantity: 3 packages Lot: 0655103 2. The manufacturer's instructions located on the package label for the BD vacutainer tubes specified a storage temperature of 4-25 degrees Celsius (C) or 40-77 degrees Fahrenheit (F). 3. In an interview on 02/07/2024 at 11:50 am in the laboratory office, the clinic manager confirmed that the temperature of the storage room was not monitored. II. Based on review of the laboratory environmental logs (January 2022 - March 2023), Medonic M-Series Hematology operator's manual, and confirmed by staff interview, the laboratory failed to ensure refrigerator acceptable temperature ranges were documented in the correct unit of measure for 455 of 455 days and were within acceptable range for 28 of 28 days. Findings Included: 1. Review of the laboratory's environmental temperature logs (January 2022-March 2023) revealed temperatures were documented in Fahrenheit(F), but the acceptable range was defined as 2-8 degrees Celsius (C). Documentation revealed 455 days when temperature was recorded in Fahrenheit. 2. Further review of the laboratory's environmental logs revealed the following days when the recorded temperature was outside the acceptable range (2-8C/36-46F). January 2023 a. Date: 01/04/2023 Temperature 32 F Outside of acceptable limit = 4 degrees b. Date: 01/05/2023 Temperature: 32 F Outside of acceptable limits = 4 degrees c. Date: 01/06/2023 Temperature: 34 F Outside of acceptable limits = 2 degrees d. Date: 01/09/2023 Temperature: 34 F Outside of acceptable limits = 2 degrees e. Date:01/11/2023 Temperature: 34 F Outside of acceptable limits = 2 degrees f. Date: 01/12/2023 Temperature: 34 F Outside of acceptable limits = 2 degrees g. Date: 01/13/2023 Temperature: 34 F Outside of acceptable limits = 2 degrees h. Date: 01/18/2023 Temperature: 29 F Outside of acceptable limits = 7 degrees i. Date: 01/25/2023 Temperature: 34 F Outside of acceptable limits = 2 degrees j. Date: 01/26/2023

	Temperature: 32 F Outside of acceptable limits = 4 degrees k. Date: 01/27/2023 Temperature: 34 F Outside of acceptable limits = 2 degrees l. Date: 01/30/2023 Temperature: 32 F Outside of acceptable limits = 4 degrees February 2023 m. Date: 02 /02/2023 Temperature: 32 F Outside of acceptable limits = 4 degrees n. Date: 02/03 /2023 Temperature: 32 F Outside of acceptable limits = 4 degrees o. Date: 02/16/2023 Temperature: 34 F Outside of acceptable limits = 2 degrees p. Date: 02/17/2023 Temperature: 32 F Outside of acceptable limits = 4 degrees q. Date: 02/20/2023 Temperature: 34 F Outside of acceptable limits = 2 degrees r. Date: 02/21/2023 Temperature: 32 F Outside of acceptable limits = 4 degrees s. Date: 02/22/2023 Temperature: 34 F Outside of acceptable limits = 2 degrees t. Date: 02/23/2023 Temperature: 34 F Outside of acceptable limits = 2 degrees March 2023 u. Date: 03/01 /2023 Temperature: 32 F Outside of acceptable limits = 4 degrees v. Date: 03/02/2023 Temperature: 32 F Outside of acceptable limits = 4 degrees w. Date: 03/08/2023 Temperature: 32 F Outside of acceptable limits = 4 degrees x. Date: 03/09/2023 Temperature: 34 F Outside of acceptable limits = 2 degrees y. Date: 03/13/2023 Temperature: 34 F Outside of acceptable limits = 2 degrees z. Date: 03/17/2023 Temperature: 32 F Outside of acceptable limits = 4 degrees aa. Date: 03/28/2023 Temperature: 32 F Outside of acceptable limits = 4 degrees bb. Date: 03/30/2023 Temperature: 34 F Outside of acceptable limits = 2 degrees 3. In an interview on 02/07 /2023 at 11:30 am in the laboratory, the clinic manager was asked if a conversion table was available to convert temperatures from F to C. Documentation of corrective action for out-of-range temperatures was requested. No evidence of a conversion to C was found (conversion of 2-8 C is 36-46 F). No corrective action was provided. III. Based on review of Medonic M-Series Hematology analyzer operator's manual, Becton Dickenson blood collection tube temperature requirements, laboratory environmental logs, and confirmed in staff interview, the laboratory failed to ensure the acceptable room temperature range met the specified requirements for instrumentation and supplies in the testing area for 24 of 24 months. Findings included: 1. Review of the operator's manual for the Medonic M- Series Hematology analyzer stated in the maintenance section titled "Instructions for Use" room temperature is (18-32 C) or 65-90 F. 2. Review of the laboratory's temperature log for 01/2022 to 12/2023 revealed an acceptable range of 18-32 C for the testing area. The required storage temperature for the BD collection tubes stated on the package label was 4-25 C (40-77 F). The laboratory's acceptable temperature range for the testing area exceeded the upper limit for the BD collection tubes. 3. In an interview on 02/07 /2024 at 11:50 am in the laboratory office, the clinic manager confirmed the laboratory's room temperature did not meet the requirement.
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 a review of laboratory policy, Medonic maintenance logs (01/2022-12 /2023), and confirmed in staff interview, the laboratory failed to follow the laboratory's policy for documentation of instrument maintenance for 2 of 24 months. Findings included: 1. Review of the laboratory's procedure manual for the Medonic M- Series Hematology analyzer in the maintenance section stated, "Instrument maintenance is performed monthly and semi-annually according to the manufacturer's

	instructions, utilizing the Boule Cleaning kit." 2. Review of instrument maintenance revealed no documentation of performance of monthly maintenance for 2 of 24 months (July 2023 and January 2024). 3. In an interview with the clinic manager on 02 /07/2024 at 11:50 am in the laboratory office confirmed the laboratory failed to document monthly maintenance.
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 review of the submitted Centers for Medicare and Medicaid (CMS) 209 form, laboratory personnel records (2022 and 2023), and confirmed in staff interview, the Technical Consultant failed to evaluate the competency of three of three testing persons. Findings included: 1. Review of the documentation located on the CMS-209 form revealed one technical consultant (TC-1). 2. Review of the laboratory's competency records revealed the following: a. Position: TP-1 Date of competency: 12 /01/2022 Assessor: TP-1 b. Position: TP-1 Date of competency: 07/20/2023 Assessor not listed on CMS-209 c. Position: TP-2 Date of competency: 01/09/2023 Assessor: Clinic Manager d. Position: TP-2 Date of competency: 01/23/2024 Assessor not listed on CMS-209 e. Position: TP-3 Date of competency: 04/18/2022 Assessor not listed on CMS-209 f. Position TP-3 Date of competency: 01/09/2023 Assessor not listed on CMS-209 3. Review of the laboratory's personnel records revealed the testing persons that performed the competency assessment did not qualify as a technical consultant. 4. In an interview 02/07/2024 at 11:50 am in the laboratory, the clinic manager confirmed the findings.