

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 42D1085486	(X3) Date Survey Completed 11/07/2023
Name of Provider or Supplier Musc Childrens Health-Moncks Corner	Street Address, City, State 5000 B Epton Plantation Drive, Moncks Corner, 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 initiated on 11/07/2023 and concluded on 11/07/2023. The facility was found not to be in compliance with the laboratory requirements of 42 CFR Part 493 with deficiencies cited.
D5293	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c)</p> <p>(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on interview and policy and document review, the laboratory failed to ensure quality assurance (QA) information was documented and maintained for 3 (2021, 2022, and 2023) of 3 years reviewed. Findings included: Review of a facility document titled "Quality Assurance Policy," dated 05/02/2014, revealed "The laboratory has an ongoing Quality Assurance Policy that is in place to monitor the quality of the laboratory, ensure the reliability of test results and to evaluate the competency of the laboratory personnel." The policy revealed "Biannual Laboratory Report: There will be a biannual report presented to the Laboratory Director that contains the following information: 1. Number of each test performed in the laboratory for the last 6 months 2. Inventory of waived tests 3. Information on proficiency testing for the quarter 4. Information on new staff 5. Anything important going on in the laboratory that the Director should know about." The policy revealed "Quarterly QA checklist: The quarterly checklist, stored [sic] the QA file on the computer, will be checked quarterly and stored in the appropriate file." Document review on 11/07/2023 at 11:00 AM revealed no records of the laboratory's QA for 2021, 2022, or 2023. During an interview on 11/07/2023 at 1:15 PM, the Practice</p>

Manager acknowledged the laboratory was unable to provide the laboratory's QA information for 2021, 2022, or 2023.

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:
Based on facility document review, manual review, and interview, the laboratory failed to document the monitoring of laboratory temperature and humidity readings for 2 (2022 and 2023) of 3 years reviewed. Findings included: Review of a manufacturer's manual for a laboratory hematology analyzer, dated April 2013, revealed the environment requirements for the analyzer called for the humidity range to be 30% to 85% and the ambient temperature at 15 degrees Celsius (C) to 30 degrees C (59 degrees Fahrenheit [F] to 86 degrees F). A review of laboratory documents on 11/07/2023 at 11:00 AM revealed there were no recorded laboratory temperature or humidity readings documented from January 2022 through November 2023. During an interview on 11/07/2023 at 1:15 PM, the Practice Manager acknowledged she was unable to provide documentation of the laboratory's temperatures or humidity for 2022 or 2023.