

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D0983971	(X3) Date Survey Completed 02/08/2023
Name of Provider or Supplier Beulaville Pediatrics	Street Address, City, State 110 East Park Drive, Beulaville, NC	
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
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on manufacturer's instructions, surveyor observation and laboratory director (LD) interview 2/8/22 the laboratory failed to label 3 vials of hematology quality control (QC) reagent with current expiration dates. Findings: Review of manufacturer's instructions for Boule Con-Diff Tri-Level hematology QC reagent revealed "Storage and Stability...Open vial stability 14 days after opening when returned to refrigerator after each use. ". At approximately 11:00 p.m. surveyor observed a plastic container on the top shelf in laboratory refrigerator containing 3 vials of Boule Con-Diff Tri-Level hematology QC reagent, Lot #22212-33,22212-32 and 2212-31. The 3 vials of QC reagent failed to be labeled with current expiration dates. Interview with LD at approximately 11:00 a.m. confirmed the 3 vials of QC reagent were not labeled with current expiration dates. She stated the vials were put into use this morning and demonstrated that they track the date in which new QC reagents are put into use on a calendar beside the hematology instrument. She also confirmed the 3 vials were not labeled with current expiration dates.</p>
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at</p>

least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on review of Medonic hematology analyzer user manual, review of 2021, 2022 and 2023 Medonic maintenance logs and interview with LD 2/8/22, the laboratory failed to document monthly maintenance of the Medonic hematology analyzer since testing began in November of 2021, a period of approximately fourteen months.

Findings: Review of Medonic user manual revealed under Section 8.2 "Monthly Cleaning...This section describes the cleaning procedures to be used to secure the correct function of the instrument on a monthly basis.". Review of Medonic maintenance logs for 2021, 2022 and 2023 revealed no documentation of the performance of monthly maintenance since testing began in November of 2021. Interview with LD at approximately 11:00 a.m. confirmed monthly maintenance was not documented. She stated she was sure the maintenance was performed because the instrument would not allow testing if not.