

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D0242687	(X3) Date Survey Completed 06/02/2025
Name of Provider or Supplier Albemarle Pediatrics	Street Address, City, State 1420 Us Highway 52 N, Suite A, Albemarle, 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>(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, surveyor observation and technical consultant (TC) interview 06/02/25, the laboratory failed to ensure 3 vials of Boule Con-Diff Tri-Level quality control (QC) reagent were labeled with an open date and new expiration date once opened. Findings: Review of manufacturer's instruction for the Boule Con-Diff Tri-Level QC reagent revealed "STORAGE AND STABILITY.... Open vial stability 14 days after opening when returned to the refrigerator after each use.". At approximately 1:00 p.m. surveyor observed 3 vials of Boule Con-Diff Tri-Level QC reagent; Lot # 22503-01, 22503-02, and 22503-03, in a paper cup on a shelf in the laboratory refrigerator. The vials were in use and not labeled with an open date and the new expiration date. Interview with TC at approximately 1:00 p.m. confirmed the 3 vials of QC reagent were in use and not labeled with an open date and the new expiration date.</p>