

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D0243602	(X3) Date Survey Completed 03/27/2026
Name of Provider or Supplier Salisbury Pediatrics	Street Address, City, State 129 Woodson Street, Salisbury, 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 surveyor observation, review of quality control (QC) reagent package insert and interview with testing personnel (TP#1), 03/27/26, the laboratory failed to label QC reagents with new expiration dates after opening. Findings: At approximately 11:15 a.m. surveyor observed, on a shelf in a clear cup of the laboratory refrigerator, 3 vials of Sysmex XN-L Check QC reagent labeled with an open date only. The 3 vials, lot #'s 60371401, 60371402 and 60371403, failed to be labeled with new expiration dates after opening. Review of reagent package insert for the Sysmex XN-L Check QC reagent revealed "Storage and shelf life after first opening...Open vials and vials which have been sampled by cap piercing will retain stability for 15 days...". Interview with TP #1 at approximately 11:15 a.m. confirmed the date written of the label of the 3 vials of QC reagent was the open date and the vials were not labeled with the new expiration date after opening. She also stated that the laboratory tracks the new expiration date on a calendar in the laboratory and they change the vials every 20 days.</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have</p>

deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on deficiency cited at D5415, review of QC reagent package insert and interview with TP #1, the laboratory failed to ensure QC reagent was not used for testing after the open expiration date of 15 days since December of 2024, a period of approximately 15 months. Findings: Review of QC reagent package insert for the Sysmex XN-L Check QC reagent revealed "Storage and shelf life after first opening... Open vials and vials which have been sampled by cap piercing will retain stability for 15 days...". Interview with TP #1 at approximately 11:15 a.m. confirmed the laboratory was performing QC with expired QC reagent. She stated the laboratory tracks the new expiration date on a calendar in the laboratory and they change the vials every 20 days. She also stated they were unaware of the 15 day stability of the QC reagent and they were told by a sales representative that the open expiration was 20 days.