

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D1012189	(X3) Date Survey Completed 05/29/2026
Name of Provider or Supplier Novant Health Twin City Pediatrics	Street Address, City, State 2821 Maplewood Avenue, Winston-Salem, 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
D6072	<p>TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(3)</p> <p>(b)(3) Adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed;</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, review of 2024, 2025, and 2026 Medonic hematology maintenance records, and interview with the TC (technical consultant) 5/29/26, and email correspondence 6/2/26, testing personnel failed to perform and document Medonic monthly cleaning as required for 5 of 29 months from January 2024 to May 2026. Review of the laboratory's "Medonic M-Series Hematology Analyzer" procedure on 5/29/26 revealed "... G. Maintenance ... 3. Monthly cleaning a. Clean the aspiration probes using an alcohol wipe. b. Fill a cup with 10 ml 2% hypochlorite (Bottle #2 from Boule Cleaning Kit) and one cup with 18 ml diluent (Recommend use of the dispense function for obtaining diluent see Section 5.5 of Medonic User's Manual; Dispense Function) c. Aspirate hypochlorite as a pre-dilute sample. Repeat aspiration for a total of 2 times. d. Run 2 blank samples by aspirating diluent as a pre-diluted sample. e. Perform a background check, in pre-dilute mode, to verify all values are within range. f. Test all three levels of control. When all control results are within acceptable limits, patient testing may commence. g. Document on the Medonic M-Series Maintenance Log. ..." Review of 2024, 2025, and 2026 Medonic maintenance logs and instrument printouts on 5/29/26 revealed there was no documentation of monthly maintenance for the following months: 1. 2024 - March, August; 2. 2025 - January December; 3. 2026 - February. During interview 5/29/26 at approximately 2:00 p.m., the TC confirmed the maintenance records were not available for review. In email correspondence on 6/2/26, the TC verified that the laboratory was unable to provide documentation of monthly cleaning for the missing months.</p>