Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D2136294	08/01/2024
Name of Provider or Supplier	**Street Address, City, State**	
Novant Health Forsyth Pediatrics Union Cross	1471 Jag Branch Boulevard, Suite 101, Kernersville, 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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on review of 2022, 2023, and 2024 hematology quality control records and interview with the TC (technical consultant) 8/1/24, the laboratory failed to retain manufacturer's assay sheets for each lot number of hematology control material used from 4/1/22 - 8/1/24. Findings: Review of 2022, 2023, and 2024 quality control records for the Medonic M-Series hematology analyzer revealed the laboratory failed to retain manufacturer's assay sheets for the following lot numbers of Boule Con-Diff control material for at least two years: 1. 2211231/2211232/2211233 2. 2220131 /2220132/2220133 3. 2220231/2220232/2220233 4. 2220331/2220332/2220333 5. 2220431/2220432/2220433 6. 2220531/2220532/2220533 7. 2220731/2220732 /2220733 8. 2221001/2221002/2221003 9. 2221031/2221032/2221033 10. 2230101 /2230102/2230103 11. 2230131/2230132/2230133 12. 2230331/2230332/2230333 13. 2230431/2230432/2230433 14. 2230731/2230732/2230733 15. 2231031/2231032 /2231033 16. 2231231/2231232/2231233 During interview at approximately 1:00 p. m., the TC confirmed the laboratory had not saved the hematology quality control assay sheets.
D3039	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(5) Quality system assessment records. Retain all laboratory quality system assessment records for at least 2 years.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's quality assessment plan, review of 2022, 2023, and 2024 quality assessment records, and interview with the TC 8/1/24, the laboratory failed to retain all quality assessment records for at least two years. Findings: Review of the laboratory's quality assessment plan revealed the plan included monitors to be completed by the laboratory on a quarterly basis and an annual assessment. Review of 2022, 2023, and 2024 quality assessment monitors revealed the following monitors were not available for review during the survey: 1. 2022 4th quarter 2. 2023 1st, 2nd, 3rd, and 4th quarters and annual assessment During interview at approximately 2:00 p. m., the TC confirmed the 2022 4th quarter and the 2023 1st, 2nd, 3rd, and 4th quarters and annual assessment records were missing.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions and review of 2022, 2023, and 2024 hematology maintenance logs 8/1/24, the laboratory failed to document required monthly maintenance for the Medonic M-Series hematology analyzer for 7 of 12 months in 2022. Findings: Review of the Medonic M-Series User's Manual "Section 8: Cleaning, Maintenance & Transport" revealed maintenance procedures to be performed daily, monthly, and every six months. Section "8.2 Monthly Cleaning" stated "This section describes the cleaning procedure to be used to secure the correct function of the instrument on a monthly basis. ..." The section included instructions for cleaning the analyzer with hypochlorite and instructions for performing the clot prevention procedure using enzymatic cleaner. Review of 2022, 2023, and 2024 Medonic M-Series maintenance logs revealed the laboratory failed to document monthly maintenance for 7 of 12 months in 2022. Monthly maintenance was not documented for the following months: February, April, May, June, July, November, December.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of MediaLab training documents, review of 2022, 2023, and 2024 bilirubin quality control records, and review of manufacturer's quality control assay sheet 8/1/24, the laboratory failed to ensure quality control was acceptable prior to reporting patient test results. Findings: Review of MediaLab "Bilirubinometer - Initial" training documents for the Reichert Unistat Bilirubinometer revealed on Slide 5 "Quality Control Two levels of control material will be processed each day prior to

	patient testing ... Controls are processed in the same manner as patients and results recorded on the QC log. If one or both control values are outside the acceptable range, check the lot # and expiration date, remix the controls and retest. If controls continue to be out of acceptable range, call your Technical Consultant or Reichert Customer Service. Do not report patients until acceptable quality control has been obtained." Review of 2022, 2023, and 2024 bilirubin quality control records revealed the laboratory used Quantimetrix Bilirubin Control - Pediatric / Level 1 & 2 (lot #131651 /131652) from 2/1/22 - 3/31/23. Review of the manufacturer's quality control assay sheet revealed the following acceptable ranges for quality control: 1. Lot #131651 (Level 1) - 9.3 - 13.9 mg/dL (milligrams per deciliter) 2. Lot #131652 (Level 2) - 19.1 - 28.6 mg/dL Review of the laboratory's bilirubin logs revealed the following acceptable ranges for quality control which were not consistent with the ranges specified by the manufacturer: 1. Lot #131651 (Level 1) - 8.9 - 13.4 mg/dL 2. Lot #131652 (Level 2) - 18.3 - 27.4 mg/dL Review of the laboratory's bilirubin logs revealed Level 1 control values were outside the manufacturer's acceptable limits on 9 days of testing (3/29/22, 3/31/22, 4/1/22, 4/4/22, 4/6/22, 7/20/22, 2/20/23, 2/21/23, and 3/3/23), and Level 2 control values were outside the manufacturer's acceptable limits on 3 days of testing (2/20/23, 2/21/23, and 3/3/23).