Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D1074713	05/25/2023
Name of Provider or Supplier	**Street Address, City, State**	
Rainbow Pediatrics Of Fayetteville - Hope Mills	4469 S Main Street, Hope Mills, 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
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures and review of 2020, 2021, 2022, and 2023 API (American Proficiency Institute) proficiency testing records, the laboratory failed to test proficiency samples in the same manner that patient specimens are routinely tested for 9 of 10 test events. Review of the laboratory's quality assessment policies and procedures revealed "... General Laboratory Systems ... Proficiency Testing PT samples are tested to the extent possible, exactly like patient specimens, i.e., the same number of times and using the same personnel and methods as for patient testing. ..." The laboratory's quality assessment policies and procedures also stated "... Panic/Alert Value Procedures ... Recheck, Remix, Rerun, repeat & report". Review of the laboratory's policies and procedures revealed the following policy for patient testing "CBC Results Testing personnel will rerun cbs's when results are out of range or there is a message on the results then all results are given to the provider and they review all cbc results and determine if the results are acceptable or if they need to be reran or if follow up lab work is required." Review of 2020, 2021, 2022, and 2023 API proficiency testing records revealed there was no documentation that proficiency samples were rerun for flags or panic values on the following samples: 1. 2020 a. 1st hematology test event - samples HSY-01, HSY-03, HSY-05;

	b. 2nd hematology test event - samples HSY-06, HSY-07, HSY-09; c. 3rd hematology test event - samples HSY-11, HSY-12, HSY-14, HSY-15. 2. 2021 a. 1st hematology test event - samples HSY-01, HSY-02, HSY-03, HSY-05; b. 2nd hematology test event - samples HSY-08, HSY-09, HSY-10; c. 3rd hematology test event - samples HSY-11, HSY-13, HSY-15. 3. 2022 a. 1st hematology test event - samples HSY-02, HSY-03, HSY-04; b. 2nd hematology test event - samples HSY-06, HSY-07, HSY-09; c. 3rd hematology test event - samples HSY-13, HSY-14, HSY-15.
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, review of 2020, 2021, 2022, and 2023 maintenance records, the absence of records, and interview with TP (testing personnel) 5/25/23, the laboratory failed to perform and document the manufacturer's specified maintenance for the Medonic M-Series hematology analyzer daily for 22 of 22 days in April 2020, and failed to perform and document the monthly maintenance for the Medonic M-Series hematology analyzer for 41 of 41 months from January 2020 to May 2023. Findings: Review of the Medonic M-series Procedure Manual revealed "...Maintenance: Daily cleaning should be performed according to the Medonic M-Series User's Manual. Instrument maintenance is performed monthly and semi-annually according to the manufacturer's instructions utilizing the Boule Cleaning kit. ... All maintenance should be documented (a maintenance log is recommended), and the documentation saved for a minimum of 2 years. ..." Review of 2020, 2021, 2022, and 2023 Medonic M-Series maintenance records revealed: 1. The laboratory failed to utilize the maintenance log provided by the manufacturer. 2. The laboratory failed to perform and document daily maintenance for 22 of 22 days in April 2020. 3. The laboratory failed to perform and document monthly maintenance for: a. 12 of 12 months in 2020; b. 12 of 12 months in 2021; c. 12 of 12 months in 2022; d. 5 of 5 months (January - May) in 2023. During interview at approximately 12: 27 p.m., TP #1 confirmed that the monthly maintenance was not documented as required.