Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0899531	03/12/2026
Name of Provider or Supplier	**Street Address, City, State**	
Fuquay Varina Pediatrics	316 Judd Place Drive, Fuquay Varina, 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
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of 2024 and 2025 American Proficiency Institute (API) proficiency testing (PT) records, lack of documentation, review of laboratory procedure and interview with clinical administrator 03/12/26, the laboratory failed to review and perform corrective action if needed for unacceptable PT results. Findings: Review of 2024 and 2025 API PT records revealed the following unacceptable PT results; 1. Platelet - 2024 Hematology/Coagulation - 3rd Event - Sample HEM-14. 2. Hematocrit - 2025 Hematology/Coagulation - 1st Event - Sample HEM-01. Review of 2024 and 2025 API PT records revealed no documentation of a review or corrective action for the unacceptable PT results. Review of laboratory procedure "Proficiency Testing" revealed "Results of each evaluation will be reviewed and signed by the laboratory director. A corrective action plan will be developed and intimated for any unsatisfactory results." The procedure fails to include review of "unacceptable" PT results. Interview with clinical administrator at approximately 11:00 a.m. confirmed the unacceptable PT results were not reviewed and/or corrective action was not documented. This deficiency was previously cited at last survey 06/28/22.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) (b) The laboratory must verify the accuracy of the following: (b)(1) Any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.

	This STANDARD is not met as evidenced by: Based on review of 2024 and 2025 American Proficiency Institute (API) proficiency testing (PT) records, lack of documentation, review of laboratory procedure and interview with clinical administrator 03/12/26, the laboratory failed to review and perform corrective action, if needed, for "ungraded" PT results. Findings: Review of 2024 and 2025 API PT records revealed the following "ungraded" PT result; 1. Platelet - 2024 Hematology/Coagulation - 1st Event - Sample HEM-03. Review of 2024 and 2025 API PT records revealed no documentation of a review and/or corrective action for the "ungraded" PT result. Review of laboratory procedure "Proficiency Testing" revealed "Results of each evaluation will be reviewed and signed by the laboratory director. A corrective action plan will be developed and intimated for any unsatisfactory results." The procedure fails to include review of "ungraded" PT results. Interview with clinical administrator at approximately 11:00 a. m. confirmed the ungraded PT results were not reviewed and/or corrective action was not documented.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (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. This STANDARD is not met as evidenced by: Based on surveyor observation, review of quality control (QC) reagent package insert and interview with clinical administrator 03/12/26, the laboratory failed to label QC reagents with new expiration dates after opening. Findings: At approximately 12:00 p. m. surveyor observed on a shelf in the laboratory refrigerator the following QC reagents labeled with an open date of 3/6. The 3 vials of Cell-Dyn 18 Plus Control QC reagents, Lot #'s L5342, N5342 and H5342, failed to be labeled with the new expiration date after opening. Review of Cell-Dyn 18 Plus Control QC reagent package insert revealed "8 Consecutive-Day Tube Stability". Interview with clinical administrator at approximately 12:00 p.m. confirmed the 3 vials of QC reagent were labeled with the open date of 3/6 and also confirmed the vials were not labeled with the new expiration date after opening. They stated the laboratory opens new vials at the start of each week.