Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0899531	06/28/2022
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
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of 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 2020 and 2021 American Proficiency Institute (API) proficiency testing (PT) records and interview with clinic manager (testing personnel (TP) #5 6/28 /22, the laboratory failed to review and evaluate unacceptable PT results for 3 of 6 API PT hematology/coagulation events. Findings: Review of APT PT records revealed the following 3 hematology/coagulation PT events had unacceptable results that were not reviewed or evaluated: 2020 API PT 3rd event - sample # HEM-13 2021 API PT 1st event - sample # HEM-02 2021 API PT 3rd event - sample # HEM-11 Interview with clinic manager (TP#5) at approximately 11:00 a.m. confirmed the laboratory failed to review and evaluate the unacceptable PT results. She stated they thought the evaluation was only necessary if API PT indicated a failure and they were unaware that all unacceptable results should be reviewed and evaluated.
D5507	BACTERIOLOGY CFR(s): 493.1261(b)(c) (b) For antimicrobial susceptibility tests, the laboratory must check each batch of media and each lot number and shipment of antimicrobial agent(s) before, or concurrent with, initial use, using approved control organisms. (b)(1) Each day tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure. (b)(2) The laboratory's zone sizes or minimum inhibitory concentration for control organisms must be within established limits before reporting patient results. (c) The laboratory must document all control procedures performed, as

	specified in this section. This STANDARD is not met as evidenced by: Based on review of laboratory quality control (QC) records and interview with clinic manager (TP #5) 6/28/22, the laboratory failed to document QC for each new lot number of bacitracin (BC) disk, approximately 134 patients were tested during the period in which QC was not documented. Findings: Review of QC records for the BC disk revealed no documentation of QC performed for Lot # 9106825. QC records indicated the lot was received approximately 12/1/19. QC was not documented until the next lot number of BC disk was received, 1/14/20, approximately 1 and a half months later. Interview with TP #5 at approximately 1:00 p.m. confirmed the laboratory failed to document QC for BC disk Lot # 9106825. She also confirmed approximately 134 patients were tested 12/1/19 through 1/14/20.