Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0239484	03/28/2024
Name of Provider or Supplier	**Street Address, City, State**	
Cary Pediatric Center	1001 Crescent Green Drive, Cary, 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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on review of 2021, 2022, 2023 and 2024 American Proficiency Institute (API) Bacteriology proficiency testing (PT) records, review of testing personnel (TP) training and competency records and interview TP #2, 3/28/24, the laboratory failed to ensure 2 of 6 TP participated in Bacteriology PT for urine and throat culture. Findings: Review of 2021, 2022, 2023 and 2024 Bacteriology API PT attestation records for urine and throat culture revealed TP #1 (laboratory director) failed to participate in 10 of 10 PT events reviewed. Review of TP #14 training and competency records revealed TP #14 began urine and throat culture testing in November of 2022. Review of 2023 and 2024 Bacteriology API PT attestation records for urine and throat culture revealed TP #14 failed to participate in 4 of 4 PT events reviewed. Interview with TP #2 at approximately 11:00 a.m. confirmed TP #1 failed to participate in 10 of 10 Bacteriology PT events and TP #14 failed to participate in 4 of 4 Bacteriology PT events.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are

	reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of laboratory quality assurance policy, review of 2021, 2022, 2023 and 2024 American Proficiency Institute (API) proficiency testing (PT) records and interview with testing personnel (TP #2), 3/28/24, the laboratory director (LD) failed to document review of results for 10 of 10 Bacteriology PT events and 5 of 9 Hematology/Coagulation PT events. Findings: Review of laboratory quality assurance policy revealed "Proficiency Testing...We will verify that all PT results have been reviewed and signed by the Lab Director.". Review of 2021, 2022, 2023 and 2024 API Bacteriology PT events revealed no documentation the LD had reviewed the results of the 1st, 2nd and 3rd events of 2021, the 1st, 2nd and 3rd events of 2022, the 1st, 2nd and 3rd events of 2023 and the 1st event of 2024. Review of 2021, 2022 and 2023 API Hematology/Coagulation PT events revealed no documentation the LD had reviewed the results of the 2nd and 3rd events of 2022 and the 1st, 2nd and 3rd events of 2023. Interview with TP #2 at approximately 11:00 a.m. confirmed there was no documentation of the LD's review of the PT events. They stated they thought the LD only needed to document their review if corrective action was required.