

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D1092438	(X3) Date Survey Completed 04/05/2024
Name of Provider or Supplier Novant Health Meadowlark Pediatrics	Street Address, City, State 5110 Robinhood Village Drive, Suite C-1, Winston Salem, 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	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>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</p> <p>This STANDARD is not met as evidenced by: Based on review of 2021, 2022, and 2023 API (American Proficiency Institute) proficiency testing records and interview with testing personnel (TP) #1 on 4/5/24, all proficiency samples for 6 of 8 proficiency testing events reviewed were tested by 1 of 3 testing personnel (TP #1). Findings: Review of 2021, 2022, and 2023 API proficiency testing records revealed TP #1 had tested all samples for 6 of 8 testing events during 2021 (3rd Hematology test event), 2022 (1st and 3rd Hematology test events), and 2023 (1st, 2nd, and 3rd Hematology test events). During interview at approximately 12:45 p.m., TP #1 confirmed that she had routinely performed the proficiency testing. She stated one of the other testing personnel works part time, so she is not always working when it is time to test the proficiency samples.</p>
D6021	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.</p>

This STANDARD is not met as evidenced by:

Based on review of the laboratory's quality assessment plan, review of 2021, 2022, and 2023 quality assessment monitors, and interview with the TC (technical consultant) 4/5/24, the laboratory director failed to ensure the quality assessment program was maintained to assure the quality of the laboratory services offered.

Findings: Review of the laboratory's quality assessment plan revealed the plan included monitors to be completed by the laboratory on a quarterly basis. Review of 2021, 2022, and 2023 quality assessment monitors revealed the 2021 2nd and 3rd quarter monitors and the 2023 2nd, 3rd, and 4th quarter monitors were missing from the records. During interview at approximately 1:45 p.m., the TC stated the 2021 2nd and 3rd quarter monitors and the 2023 2nd, 3rd, and 4th quarter monitors were missing from the records because the laboratory did not complete them.