

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0682685	(X3) Date Survey Completed 11/21/2024
Name of Provider or Supplier Orchard Park Pediatrics Pc	Street Address, City, State 3725 North Buffalo Road, Suite A, Orchard Park, NY	
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
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on review of Centers for Medicare & Medicaid Services (CMS) Proficiency Testing (PT) Certification and Survey Provider Enhanced Reporting system (CASPER 0096D) and College of American Pathologists (CAP) PT summary reports, Standard Operating Procedures (SOPs), as well as interviews with the Laboratory Director (LD) and Testing Personnel (TP), the laboratory failed to enroll in a PT program for the bacteriology subspecialty. FINDINGS: 1. There was no documentation of 2024 PT enrollment, performance, and result reporting for the bacteriology subspecialty. 2. It was noted that documentation was available for 2022 and 2023 PT bacteriology subspecialty enrollment, performance, and result reporting. 3. The current, approved SOPs did not include instructions for performing bacteriology subspecialty PT and result reporting. 4. The LD and TP confirmed the findings on November 21, 2024, at approximately 10:30 A.M.</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p>

At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:

Based on review of laboratory records and SOPs, lack of urine culture colony count verification documentation, as well as interviews with the LD and TP, the laboratory failed to establish and maintain the accuracy of its testing procedures. FINDINGS: 1. There was no documentation of minimum twice annual urine culture colony count verifications for 2023 and 2024. 2. It was noted that documentation was available for 2022 twice annual urine culture colony count verifications. 3. The current, approved SOPs do not include instructions for performing such activity. 4. The LD and TP confirmed the findings on November 21, 2024, at approximately 10:00 A.M.

D6015

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)

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) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.

This STANDARD is not met as evidenced by:

Based on CMS PT CASPER 0096D and CAP PT summary reports from 2024, SOPs, as well as interviews with the LD and TP, the LD failed to ensure that the laboratory was enrolled in a PT program for the bacteriology subspecialty. Refer to D2000.