

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  33D0984877	<b>(X3) Date Survey Completed</b>  01/10/2025
<b>Name of Provider or Supplier</b>  Allied Pediatrics & Family Medicine	<b>Street Address, City, State</b>  2154 New Bridge Road, Bellmore, NY	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2000</b>	<p><b>ENROLLMENT AND TESTING OF SAMPLES</b> 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 &amp; Medicaid Services (CMS) Proficiency Testing (PT) Certification and Survey Provider Enhanced Reporting system (CASPER 0155D), American Proficiency Institute (API) enrollment report, Standard Operating Procedures (SOPs), lack of proficiency testing (PT) records as well as interview with Office Manager (OM), the laboratory failed to enroll in an approved PT program for the Bacteriology subspecialty and Hematology specialty. <b>FINDINGS:</b> 1. The laboratory performed on-site throat culture and Complete Blood Count (CBC) laboratory testing and result reporting. 2. There was no documentation of Hematology PT performance or results for the first event of 2024. 3. There was no documentation of Bacteriology PT performance or results for calendar year 2024. 4. The current, approved SOPs did not include instructions for performing such activity. 5. The OM confirmed the findings on January 10, 2025, at approximately 12:00 P.M.</p>
<b>D2016</b>	<p><b>SUCCESSFUL PARTICIPATION</b> CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a</p>

proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.

This CONDITION is not met as evidenced by:  
Based on CMS PT CASPER 0155D summary reports, the laboratory failed to successfully participate in the CMS approved PT program for two of three consecutive testing events in the Bacteriology subspecialty in 2023 resulting in unsuccessful performance. Refer to D2028.

**D2028**

**BACTERIOLOGY**  
CFR(s): 493.823(e)

(e) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:  
Based on CMS PT CASPER 0155D summary reports from 2023, the laboratory failed to achieve satisfactory performance (80% or greater) for two of three consecutive testing events for the subspecialty Bacteriology. FINDINGS: a. A review of the CASPER 155 report revealed the following unsatisfactory scores: 1. Bacteriology Subspecialty: 2023 Second Event = 0% 2023 Third Event = 0%

**D5439**

**CALIBRATION AND CALIBRATION VERIFICATION**  
CFR(s): 493.1255(b)

(b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an

unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:  
Based on review of calibration records, SOPs, as well as interview with OM, the laboratory failed to perform and document calibration every six months for calendar years 2023 and 2024. FINDINGS: 1. Calibration and documentation was performed for August 2023. 2. There was no documentation of calibration performance for 2024. 3. These are contrary to instructions indicated in the current, approved SOPs. 4. Approximately 2596 patient specimens were processed and results reported during the respective period. 5. The OM confirmed the findings on January 10, 2025, at approximately 11:30 A.M.

**D6000**

**MODERATE COMPLEXITY LABORATORY DIRECTOR**  
CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:  
Based on review of CMS PT CASPER 0155D summary reports from 2023 and API enrollment report, the laboratory director (LD) failed to provide overall management and direction of the laboratory services. Refer to D5439 and D6016.

**D6016**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(4)(i)

(e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:  
Based on review of CMS PT CASPER 0155D 2023 summary reports and API enrollment report, the LD failed to ensure successful participation in an HHS approved proficiency testing program. Refer to D2028.