

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D0718167	(X3) Date Survey Completed 02/19/2025
Name of Provider or Supplier Pediatric Associates Pc	Street Address, City, State 7720 N 16th St #110, Phoenix, AZ	
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>(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.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records from 2023 and 2024 and interview with the facility personnel, the laboratory failed to test PT samples by testing personnel who routinely perform patient testing in the laboratory, using the laboratory's routine methods. Findings include: 1. The laboratory participates in 3 PT events annually for testing performed under the specialty of Microbiology. 2. The CMS-209, Laboratory Personnel Form presented during the survey conducted on 2/19/25 listed five testing personnel who routinely perform patient testing. 3. Interview with testing personnel during the survey confirmed that the PT samples were not rotated among the 5 testing personnel in the laboratory and that the same testing personnel: initials "DL" performed PT testing for every PT event from 2023-2024. 4. The facility personnel interviewed on 2/19/25 at 11:00 AM confirmed that the same individual participated in each testing event as indicated above.</p>
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on review of proficiency testing (PT) records from 2023 and 2024 and interview with facility personnel, the laboratory director and testing personnel failed to sign the PT attestation statements. Findings include: 1. The laboratory performs testing in the speciality of Microbiology with an annual test volume of 900. 2. The PT attestation statements presented for review for the first, second and third events of 2023 and 2024 lacked the signatures of the laboratory director and testing personnel. 3. The facility personnel interviewed on 2/19/25 at 11:00 AM confirmed that the PT attestation statements indicated above were not signed by the laboratory director and testing personnel.

D5211

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(a)

The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

This STANDARD is not met as evidenced by:
Based on review of Proficiency Testing (PT) records from 2023 through 2024 and interview with the facility personnel, the laboratory failed to provide a documented review of PT results from the 1st, 2nd, and 3rd testing events of 2023 and 2024. Findings include: 1. The laboratory performs patient testing under the specialty of Microbiology. The laboratory performs 900 tests annually. 2. No evidence, either by written comment or signature, was presented during the survey conducted on 2/19/25 to indicate the laboratory director or other laboratory personnel reviewed the PT results for the 1st, 2nd, or 3rd testing events of 2023. 3. No evidence, either by written comment or signature, was presented during the survey conducted on 2/19/25 to indicate the laboratory director or other laboratory personnel reviewed the PT results for the 1st, 2nd, or 3rd testing events of 2024. 4. The facility personnel interviewed on 2/19/25 at 11:00 AM confirmed the PT results indicated above were not reviewed by laboratory personnel.

D5407

PROCEDURE MANUAL
CFR(s): 493.1251(d)

(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's policy and procedure manual and interview with the facility personnel, the laboratory failed to have the current laboratory director approve, sign and date test procedures before use. Findings include: 1. The current laboratory director indicated in the CLIA Federal Database and assigned on the CMS-209, Laboratory Personnel Form presented for review during the survey has been serving as laboratory director since 5/5/2023. 2. The policy and procedure manual presented for review during the survey conducted on 2/19/25 was not approved, signed and dated by the current laboratory director. 3. The facility personnel interviewed on 2/19/25 at 12:20 PM confirmed that the policy and procedure manual indicated above was not approved, signed and dated by the current laboratory director. 4. The laboratory performs patient testing under the specialty of Microbiology with an annual test volume of 900.

<p>D6029</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11)</p> <p>(e)(11) Ensure that prior to testing patients specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results;</p> <p>This STANDARD is not met as evidenced by: Based on lack of initial training documentation for one out of one testing personnel (TP-5) and interview with the facility personnel, the laboratory director failed to ensure that prior to testing patients' specimens, all personnel have the appropriate training for the type and complexity of services offered. Findings include: 1. No initial training documentation was presented for review for one out of one testing personnel (TP-5). 2. The facility personnel interviewed on 2/19/25 at 10:30 AM confirmed the laboratory failed to provide documentation of initial training for TP-5 as indicated above. 3. The laboratory performs 900 patient tests annually under the specialty of Microbiology.</p>
<p>D6053</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>(b)(9) Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.</p> <p>This STANDARD is not met as evidenced by: Based on lack of performance evaluation documentation from 2024 and interview with the facility personnel, the technical consultant failed to evaluate and document the performance of one out of one testing personnel, at least semiannually during the first year the individuals tested patient specimens. Findings include: 1. No semiannual competency evaluation documentation was presented for review for one out of one testing personnel (TP-5) who began patient testing in January 2024. 2. The facility personnel interviewed on 2/19/25 at 10:30 AM confirmed the technical consultant failed to perform and document a semiannual competency evaluation for the testing personnel indicated above. 3. The laboratory performs 900 tests annually under the specialty of Microbiology</p>
<p>D6054</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>(b)(9) Thereafter, evaluations must be performed at least annually</p> <p>This STANDARD is not met as evidenced by: Based on lack of competency evaluation documentation for review from 2023 and 2024 and interview with the facility personnel, the technical consultant failed to evaluate and document the performance of individual responsible for moderate complexity testing at least annually. Findings include: 1. No annual competency evaluation documentation from 2023 and 2024 was presented for review for four out of five testing personnel who perform testing under the specialty of Microbiology. 2.</p>

The facility personnel interviewed on 2/19/25 at 10:30 AM confirmed the technical consultant failed to evaluate and document the performance of the above personnel at least annually during 2023 and 2024..