

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  07D0099462	<b>(X3) Date Survey Completed</b>  02/27/2019
<b>Name of Provider or Supplier</b>  Pediatric Healthcare Associates	<b>Street Address, City, State</b>  99 Hawley Ln, Stratford, CT	
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>D5217</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to verify the accuracy bi-annually for the cold agglutinin screen in the subspecialty of general immunology. Findings include: 1. Record review of the laboratory's 2017 and 2018 proficiency testing results on 2/27/19 revealed documentation of biannual verification for accuracy of the cold agglutinin screen was not available. 2. Staff interview with testing personnel #1 on 2/27/19 at 10:00 AM confirmed the above findings. 3. The laboratory performs 95 cold agglutinin tests annually.</p>
<b>D5805</b>	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory failed to ensure an</p>

appropriate test record in the subspecialty of general immunology. Findings include:

1. Record review on 2/27/19 of patient #1 encounter record for 12/26/18 revealed the following test result: "A serum cold agglutinins for *Mycoplasma pneumoniae* was positive."
2. Record review of the 'Rapid Cold Agglutinin Test (Garrow)' procedure on 2/27/19 revealed the following:
  - a. Specimen type is whole blood.
  - b. Results are reported as positive (presence) or negative (no agglutination).
3. Record review on 2/27/19 of an article, 'A Rapid Test for the Presence of Increased Cold Agglutinins', Garrow, *British Medical Journal*: July 26, 1958 revealed:
  - a. The article was used as the reference for the above procedure.
  - b. The rapid test is for the presence of increased cold agglutinins.
  - c. *Mycoplasma pneumoniae* is not specifically mentioned in the article.
4. Staff interview with testing personnel #2 on 2/27/19 at 10:10 AM confirmed the above findings.
5. The laboratory performs 95 cold agglutinin tests annually.