

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D0099462	(X3) Date Survey Completed 07/20/2023
Name of Provider or Supplier Pediatric Healthcare Associates	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to establish competency assessment policies and procedures to assess competency for the regulatory responsibility of the technical consultant (TC). Findings include: 1. Record review on 07/20/2023 of the CMS 209 Laboratory Personnel Report, revealed 1 of 1 TC. 2. Record review on 07/20/2023 of the staff training and competency files revealed lack of competency assessment documentation for the regulatory position of TC. 3. Staff interview on 07/20/2023 at 9:45 AM with the TC confirmed the above findings. The TC further commented that he/she was unaware that a TC competency assessment is a regulatory requirement. 4. The laboratory performs 6,211 complete blood counts annually in the specialty of hematology and one test annually in the subspecialty of general immunology.</p>
D5217	<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 ensure the accuracy of the cold agglutinin test system twice annually in the subspecialty of</p>

general immunology. Findings Include: 1. Record review on 07/20/2023 of the 'Cold Agglutinin Biannual Assessment Log Sheet' revealed the following: a. One assessment completed on 06/29/2022. b. Lack of documentation of biannual assessment of the cold agglutinin test in 2022. 2. Record review on 07/20/2023 of the 'Rapid Cold Agglutinin Test Procedure' revealed the following: a. 'Lab evaluation: performance of biannual testing for verification of test results'. b. 'For one positive and one negative blood cold agglutinin test results in the Stratford lab, a whole blood specimen will be obtained and sent to Quest for hemagglutination (HA), every six months'. 3. Staff interview on 07/20/2023 at 10:09 AM with the technical consultant confirmed the above findings. 4. The laboratory performs one cold agglutinin test annually in the subspecialty of general immunology.