

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0121068	(X3) Date Survey Completed 12/19/2023
Name of Provider or Supplier Allergy & Asthma Of South Jersey	Street Address, City, State 1122 N High Street, Millville, NJ	
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
D3009	<p>FACILITIES CFR(s): 493.1101(c)</p> <p>The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.</p> <p>This STANDARD is not met as evidenced by: Based on an in-office review of the laboratory's requirements for a New Jersey State Clinical Laboratory License (NJCLL) under New Jersey Statutes Annotated: N.J.S.A. 45:9-42.28. License; necessity; categories, the laboratory failed to maintain a NJCLL for 2023. The Program Manager for the Clinical Laboratory Improvement Services (CLIS) confirmed on 12/18/23, prior to the recertification survey, that the laboratory did not have a NJCLL license for 2023 or any prior years. The Laboratory Director confirmed on 12/19/23 at 11:30 am that the laboratory did not maintain a NJCLL for 2023 or any prior years.</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 surveyor review of Biannual Assessment (BA) records and interview with the Laboratory Director (LD), the laboratory failed to verify the accuracy and reliability of nasal mucosal, conjunctival mucosal and sputum allergic cell testing twice annually from 4/22/21 to the date of the survey. The findings include: 1. The BA for nasal mucosal, conjunctival mucosal and sputum allergic cell testing in 2021, 2022 and 2023 was performed by the LD rereading previously read slides instead of</p>

sending slides to a reference laboratory for split sample testing. 3. The LD confirmed on 12/19/23 at 11:00 am that the laboratory did not perform BA twice annually for nasal mucosal, conjunctival mucosal and sputum allergic cell testing as stated above.