

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2176939	(X3) Date Survey Completed 07/24/2024
Name of Provider or Supplier Goldenpoint Solutions Llc	Street Address, City, State 153 Cahaba Valley Parkway, Pelham, AL	
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
D5215	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).</p> <p>This STANDARD is not met as evidenced by: Based on a review of the API (American Proficiency Institute) proficiency testing (PT) records, corrective action documentation, and an interview with the General Supervisor (GS), the laboratory failed to ensure PT results were submitted before the PT provider's deadline. This was noted for one of three possible Immunology events in 2023. The findings include: 1. A review of the API PT records revealed a score of 0% and "Failure to participate" on 2023 Immunology Event 1, with a required submission date of 4/12/2023. 2. A review of the corrective action documentation revealed the GS did not submit the 2023 Immunology Event 1 PT results until 6/13 /2023. 3. During an interview at 11:32 AM on 7/23/2024, the GS confirmed the above findings.</p>
D6017	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(ii)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program.</p>

This STANDARD is not met as evidenced by:

Based on reviews of the API (American Proficiency Institute) proficiency testing records (PT), corrective action documentation, and an interview with the General Supervisor, the Laboratory Director failed to ensure PT results were submitted before the deadline established by the PT provider. This was noted for one of three possible Immunology PT events in 2023. The findings include: Refer to D 5215.