

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2176939	(X3) Date Survey Completed 10/12/2022
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
D6013	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;</p> <p>This STANDARD is not met as evidenced by: Based on a review of the installation and validation records for the Sysmex XN-1000 Hematology analyzer, and an interview with the Technical Consultant, the surveyor determined the Laboratory Director failed to document review and approval of the procedures as verification of the manufacturer's performance specifications before patient testing began. This affected one of three new instruments performing moderate-complexity tests. The findings include: 1. A review of the validation records for the Sysmex XN-1000 Hematology analyzer revealed no documentation (signature and date) of the Laboratory Director's review and approval of the procedures verifying the manufacturer's performance specifications. Patient CBC (Complete Blood Count) testing began on 9/8/2022. 2. During an interview on 10/12/2022 at 2:00 PM, the Technical Consultant stated he had signed the validation because he was the Laboratory Director's designee. The surveyor explained only the Laboratory Director can approve new test procedures; this responsibility cannot be delegated. SURVEYOR ID#32558 Licensure and Certification Surveyor</p>