

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2208239	(X3) Date Survey Completed 05/27/2021
Name of Provider or Supplier Health Partners Of New Site	Street Address, City, State 12761 Hwy 22 East, Daviston, 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 XP-300 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 one new instruments performing moderate-complexity tests. The findings include: 1. A review of the 1/26/2021 validation records for the Sysmex XP-300 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 3/5/2021. 2. During a review of the records, and an interview on 5/27/2021 at 10:30 AM, the Technical Consultant confirmed the above noted findings. SURVEYOR ID #32558 Licensure and Certification Surveyor</p>