

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D2127677	<b>(X3) Date Survey Completed</b>  03/02/2022
<b>Name of Provider or Supplier</b>  Anniston Care Plus Llc	<b>Street Address, City, State</b>  700 Quintard Ave, Anniston, AL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D6013</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> 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 reviews of the validation records for the Medonic M Series (SN48442) Hematology analyzer, patient logs and an interview with the Laboratory Supervisor, the surveyor determined the Laboratory Director failed to document approval of the validation as verification of the manufacturer's performance specifications before patient testing began. The Medonic was used for eight days of patient CBC (Complete Blood Count) testing before the verification data was reviewed/approved by the Laboratory Director. The findings include: 1. A review of the Hematology records revealed validation procedures on the new Medonic M Series were performed on 8/4/2020, and testing personnel began using the new Medonic for patient testing on 8/5/2020. However, the Laboratory Director did not review and approve the verification procedures until 8/13/2020. 2. A review of the patient data logs for the Medonic Hematology analyzer revealed 76 patient CBC's were performed from 8/5/2020 through 8/12/2020. 3. During an interview on 3/2/2022 at 4:00 PM, the Laboratory Supervisor confirmed the above noted findings. SURVEYOR ID#32558 Licensure and Certification Surveyor</p>