

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  44D0309601	<b>(X3) Date Survey Completed</b>  08/08/2024
<b>Name of Provider or Supplier</b>  Beacon Health Alliance, Pc	<b>Street Address, City, State</b>  4519 Hixson Pike, Hixson, TN	
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>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 observation of the laboratory, review of validation records for the Beckman Coulter DxH 520 hematology instrument, and staff interview, the lab director failed to review and approve the validation records for the Beckman Coulter DxH 520 hematology instrument with patient testing being performed since 01.23.2024. The findings include: 1. Observation of the laboratory on 08.08.2024 at 09:30 a.m. revealed the Beckman Coulter DxH 520 (serial# 83626980) in use for Complete Blood Count patient testing. 2. A review of the validation records performed for the Beckman Coulter DxH 520 revealed that the laboratory director did not review or approve the validation records. 3. An interview with the technical consultant on 08.08.2024 at 2:30 p.m. confirmed that the laboratory director had not reviewed or approved validation records for the Beckman Coulter DxH 520 instrument prior to patient testing, which began on 01.23.2024.</p>