

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D1026713	<b>(X3) Date Survey Completed</b>  03/27/2018
<b>Name of Provider or Supplier</b>  Alex City Internal Medicine	<b>Street Address, City, State</b>  3368 Highway 280 Suite 220, Alexander City, 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>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 records for the Hematology analyzer, Beckman Coulter Act diff 2, and an interview with Testing Personnel #1 (TP #1), the surveyor determined the laboratory director failed to ensure the verification procedures, performed during installation of the analyzer, were adequate to verify the manufacturer's specifications and claims of instrument performance. This failure was evident by lack of the director's signature on the installation records. This affected one of one instrument installation, which occurred during the survey review period, 3/01/2016 - 3/27/2018. The findings include: 1. During the initial tour of the laboratory, TP #1 identified the Act Diff 2 as a new Hematology analyzer, installed in December of 2017. 2. A review of the installation records, which included accuracy, precision and reportable range studies, failed to include the laboratory director's signature as an indication of review of the verification studies and approval of use of the instrument in the laboratory. 3. In an interview on 3/27/18 at 12:54 PM, TP #1 confirmed the director had not signed the installation and verification records; though he had reviewed the documents. Patricia Watson, BS, MT (ASCP) Licensure and Certification Supervisor</p>