

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  31D0901923	<b>(X3) Date Survey Completed</b>  05/21/2019
<b>Name of Provider or Supplier</b>  Regional Cancer Care Associates	<b>Street Address, City, State</b>  210 S Shore Rd, Marmora, NJ	
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 surveyor review of the Performance Specification (PS) records and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to ensure that PS procedures performed on the Beckman Coulter Act 2 dif analyzer were adequate from May 2018 to the date of survey. The findings include: 1. The LD did not review and sign the precision results. 2. There was documented evidence accuracy was performed. 3. There was no documented evidence the reference range was verified. 4. The TP #1 listed on CMS form 209 confirmed on 5/21/19 at 10:00 am that PS records were not adequate.</p>