

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 31D0108387	<b>(X3) Date Survey Completed</b> 11/22/2021
<b>Name of Provider or Supplier</b> Regional Cancer Care Associates	<b>Street Address, City, State</b> 1 Clara Maass Drive, Belleville, 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>D5407</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM) and interview with the Testing Personnel (TP) , the laboratory failed to have an approved, signed and dated PM by the LD from 3/12/19 to the date of the survey. The TP # 6 as listed on CMS form 209 confirmed on at 11:30 am a PM signed by the LD was not available.</p>
<b>D5415</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation of Quality Control (QC) material in use, review of the Sysmex Control Kit Manufacture Package Insert (MPI) and interview with the Testing Personnel (TP), the laboratory failed to put expiration dates on QC material for the Hematology tests at the time of survey. The findings include: 1. The expiration date of the QC material shortens once opened. 2. The laboratory did not put new expiration</p>

dates on the Sysmex controls in use. 3. The TP # 6 as listed on CMS form 209 confirmed on 11/22/21 at 11:15 am the laboratory failed to put expiration dates on the control material. Note: This is a repeat deficiency. It was cited on 3/12/19