

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0680189	(X3) Date Survey Completed 04/29/2025
Name of Provider or Supplier Regional Cancer Care Associates	Street Address, City, State 776 East 3rd Avenue, Roselle, NJ	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), Quality Control Records (QCR) and interview with the Testing Personnel (TP), the laboratory failed to follow the PM for "Quality Control" from 4/23/24 to 4/23/25. The findings include: 1. The PM stated "14. If the instrument generates a Levy-Jennings Chart - it will be printed and saved." 2. The laboratory runs three levels of controls on the sysmex XN430 analyzer. a) 1/2/25 - 1/30/25 had a Levy-Jennings graph for level one control only. b) 2/3/25 - 2/27/25 had a Levy-Jennings graph for level one control only c) 3/3/25 - 3/12/25 had a Levy-Jennings graphs for level two and three control only d) There where no Levy-Jennings graphs from 3/13/25 -3/31/25 3. The PM stated "18. The Laboratory Director or Techincal Consultant will review and sign the QC logs each month" a) There was no documented evidence the above mentioned procedure was performed. 4. The TP confirmed on 4/29/25 at 12:30 pm that the laboratory did not follow the PM.</p>