

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0680189	(X3) Date Survey Completed 04/11/2023
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
D3037	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4)</p> <p>Proficiency testing records. Retain all proficiency testing records for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of Proficiency Testing (PT) records and interview with the Office Manager (OM), the laboratory failed to retain copies of all PT records for testing performed with the American Association of Bioanalysts (AAB) in the calendar year 2021. The findings include: 1. The laboratory did not have graded PT results for Q 1,2 and 3 2021 Hematology. 2. The laboratory did not have the attestation statements for Q 1,2 and 3 2021 Hematology. 3. The laboratory did not have work records Q 1,2 and 3 2021 Hematology. 4. The OM confirmed on 4/14/23 at 1:10 pm that PT records were not retained.</p>
D5309	<p>TEST REQUEST CFR(s): 493.1241(e)</p> <p>If the laboratory transcribes or enters test requisition or authorization information into a record system or a laboratory information system, the laboratory must ensure the information is transcribed or entered accurately.</p> <p>This STANDARD is not met as evidenced by: Based on review of Test Reports (TR), Electronic Medical Records (EMR) and interview with the Office Manager (OM), the laboratory failed to ensure that information from TR was manually transcribed accurately into the EMR for all tests from 7/18/19 to the date of the survey. The OM confirmed on 4/11/23 at 1:15 pm that the laboratory did not ensure information was manually transcribed accurately.</p>

D5469

CONTROL PROCEDURES

CFR(s): 493.1256(d)(10)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on surveyor review of Quality Control (QC) records and interview with the Testing Personnel (TP), the laboratory failed to verify commercial QC material with each new lot and/or shipment of QC used for Hematology tests performed on Sysmex XN-L 430 analyzer on the date of survey. The finding includes: 1. There was no documented evidence that QC was verified before being put into use. 2. The TP confirmed on 4/11/23 at 12:20 pm that the QC material was not verified before putting in use.