| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 31D0894569 | 10/04/2018 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Regional Cancer Care Associates | 108 Bilby Road, Suite 306, Hackettstown, 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 |
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| **D2015** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(5)(6)<br><br>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of the Proficiency Testing (PT) records and interview with the Laboratory Director (LD), the laboratory failed to ensure that the attestation statements for Complete Blood Count (CBC) tests performed with American Association of Bioanalysts (AAB) were signed by the Testing Personnel (TP) for the calendar years 2017 and 2018. The LD confirmed on 10/4/18 at 1:45 pm that the TP did not sign the AAB PT surveys for the above mentioned surveys. |
| **D5469** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(10)(g)<br><br>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 |

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| | 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.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of the Quality Control (QC) records and interview with the Laboratory Director (LD), the laboratory failed to verify that assayed QC material was within the acceptable range before it was put into use for analytes ran on the Coulter AcT diff2 analyzer in April 2018. The findings include: 1. Coulter 4C - ES Cell control lot # 068900 expired on 4/23/18 but the new control lot #069500 was verified on 4/26/18. 2. Approximately 10 - 15 patients were run between 4/24/18 and 4/25/18. 3. The LD confirmed on 10/4/18 at 1:40 pm that the laboratory did not verify QC material before use. |
| **D6029** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(11)<br><br>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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of the Personnel Files and interview with the Laboratory Director (LD), the LD failed to have training documented for two out of three Testing Personnel (TP) from January 2017 to the date of the survey. The LD confirmed on 10 /4/18 at 1:10 pm that all TP did not have training records. |