| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 44D2077868 | 03/23/2018 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Care Rite, Pllc | 521 Hwy 51 North, Suite A, Ripley, TN | |

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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| **D0000** | A complaint survey was performed on March 13, 2018. Care Rite, PLLC 44D2077868 was not in compliance with 42 CFR Part 492, Requirements for Laboratories; with conditions cited at 42 CFR 493.801 Enrollment and testing of samples. Laboratory A is Care Rite PLLC 44D2036174 located at 1445 Hwy 51 ByPass, Suite A, Dyersburg, TN 38024. Laboratory B is Care Rite PLLC 44D2077868 located at 521 Hwy 51, North Suite A, Ripley, TN 38063. Laboratory A sent to Laboratory B the American Proficiency Testing (API) 2017 event 3 complete blood count (CBC) proficiency testing (PT) samples on November 27, 2017 prior to the December 1, 2017 result due date. Laboratory B performed the API 2017 event 3 PT samples on November 28, 2017, but did not share the results with Laboratory A. Laboratory B was not enrolled in proficiency testing during the 2017 event 3 and wanted to use Laboratory A's PT samples as quality assessment. Laboratory B did not share their results with Laboratory A. Laboratory A reported their own CBC PT results to API on November 20, 2017. Laboratory B did not notify Centers for Medicare and Medicaid (CMS) of the receipt of the PT samples. |
| **D2000** | ENROLLMENT AND TESTING OF SAMPLES<br>CFR(s): 493.801<br><br>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. |

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| | This CONDITION is not met as evidenced by:<br>The laboratory failed to notify CMS the receipt of the PT samples from Laboratory A. (Refer to D2013) |
| **D2013** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(4)<br><br>The laboratory must not send proficiency testing samples or portions of proficiency testing samples to another laboratory for any analysis for which it is certified to perform in its own laboratory. Any laboratory that CMS determines intentionally referred a proficiency testing sample to another laboratory for analysis may have its certification revoked for at least one year. If CMS determines that a proficiency testing sample was referred to another laboratory for analysis, but the requested testing was limited to reflex, distributive, or confirmatory testing that, if the sample were a patient specimen, would have been in full conformance with written, legally accurate and adequate standard operating procedures for the laboratory's testing of patient specimens, and if the proficiency testing referral is not a repeat proficiency testing referral, CMS will consider the referral to be improper and subject to alternative sanctions in accordance with 493.1804(c), but not intentional. Any laboratory that receives a proficiency testing sample from another laboratory for testing must notify CMS of the receipt of that sample regardless of whether the referral was made for reflex or confirmatory testing, or any other reason.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation of the laboratory, review of the quality assessment (QA) records, the corrective action logs, the complete blood count (CBC) instrument printouts, interview with testing personnel number one and American Proficiency Institute (API) customer service, the laboratory failed to ensure that the laboratory did not receive proficiency testing samples from another laboratory; and, failed to notify CMS the receipt of the PT samples from Laboratory A, for testing in 2017. The findings include: 1) Observation of the laboratory on March 23, 2018 at 11:50 a.m. revealed the Sysmex XP-300 (serial number B2036) in use for patient testing. 2) Review of the December 12, 2017 QA records revealed the following technical consultant statement, "API 2017 event 3- order did not get done. will run D'burg post submission deadline & I will grade". 3) Review of the January 3, 2018 corrective action revealed the following technical consultant statement, "API- PT order not received in time to get event 2017 #3. Testing personnel instructed to get samples from Care Rite in Dyersburg & run them after submission deadline. However deadline was incorrectly interpreted & samples were run before submission deadline. No results were shared by the labs. Training done on correct PT protocol. Ripley now enrolled in 2018 PT". 4) Review of the November 28, 2017 CBC instrument printouts revealed samples ID listed the same as the 2017 event 3 PT samples ID (HYS11, HYS12, HYS13, HYS14, and HYS15) with documentation of comparison. Corrective action stated, "Borrowed samples to run & returned so no repeat available on #13 mono". 5) Interview on March 23, 2018 at 12:30 p.m. with testing personnel number one confirmed the Dyersburg sister laboratory proficiency testing samples were received in this (Ripley) laboratory on November 27, 2017. The borrowed PT samples were tested in the Ripley laboratory on November 28, 2017. CMS was not notified receipt of the PT samples for testing. 6) Interview on March 28, 2018 at 10:06 am with API customer service confirmed the 2017 event three result due date was December 1, 2017. |
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| **D6000** | MODERATE COMPLEXITY LABORATORY DIRECTOR<br>CFR(s): 493.1403<br><br>The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.<br><br>This CONDITION is not met as evidenced by:<br>The laboratory director failed to ensure the laboratory enroll in PT for complete blood counts (CBC) during the 2017 event three. (Refer to D6015) |
| **D6015** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(4)<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)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation of the laboratory, review of quality assessment (QA) records, one patient report and interview with testing personnel number one, the laboratory director failed to ensure the laboratory enroll in PT for complete blood counts (CBC) during the 2017 event three. The findings include: 1) Observation of the laboratory on March 23, 2018 at 11:50 a.m. revealed the Sysmex XP-300 (serial number B2036) in use for patient testing. 2) Review of the December 12, 2017 quality assessment (QA) records revealed the 2017 event 3 PT was not ordered for the December 1, 2017 result due date. 3) Review of one patient report revealed a CBC was reported on September 28, 2017. 4) Interview on March 23, 3018 at 11:55 a.m. with testing personnel number one confirmed the laboratory director failed to ensure the laboratory was enrolled in PT for the CBC in 2017 event three and that patient CBC testing began September 28, 2017. |