

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  44D2036174	<b>(X3) Date Survey Completed</b>  03/23/2018
<b>Name of Provider or Supplier</b>  Care Rite Pllc	<b>Street Address, City, State</b>  1445 Hwy 51 Bypass Ste E, Dyersburg, TN	
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>D0000</b>	<p>A complaint survey was performed on March 13, 2018. Care Rite, PLLC 44D2036174 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) samples on November 27, 2017 prior to the December 1, 2017 result due date. Laboratory B performed the API 2017 event 3 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.</p>
<b>D2000</b>	<p><b>ENROLLMENT AND TESTING OF SAMPLES</b> CFR(s): 493.801</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Laboratory A failed to ensure the 2017 event three PT CBC samples were not sent to Laboratory B, prior to the result due date December 1, 2017. (Refer to D2013)</p>

**D2013**

**TESTING OF PROFICIENCY TESTING SAMPLES**

CFR(s): 493.801(b)(4)

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.

This STANDARD is not met as evidenced by:

Based on surveyor record review, interview with testing personnel number one and API customer service, the Laboratory A failed to ensure the PT 2017 event three CBC samples were not sent to Laboratory B prior to result due date, in December 2017. The findings include: 1) Observation of the laboratory on March 23, 2018 at 1:58 pm revealed the Sysmex XP-300 (serial number B1821) CBC instrument in use for patient testing. 2) Review of the 2017 event three API PT records and CBC instrument printout records revealed testing personnel number one performed PT sample testing on November 20, 2017 for sample numbers HSY11, HSY12, HSY13, HSY14, and HSY15. Laboratory A CBC instrument results were submitted to API on November 20, 2017. 3) Interview on March 23, 2018 at 2:00 pm with testing personnel number one confirmed that on November 27, 2017, the (sister lab) Laboratory B testing personnel called Laboratory A stating the technical consultant for both Laboratory A and B, was sending an internal courier to collect the 2017 event three PT CBC samples be transported to Laboratory B, located approximately 23 miles /28 minutes away. 4) Laboratory B did not share their results with Laboratory A. Laboratory A reported their own CBC PT results to API. 5) Interview with API customer service on March 28, 2018 at 10:06 am confirmed the PT 2017 event 3 result due date was December 1, 2017.

**D6000**

**MODERATE COMPLEXITY LABORATORY DIRECTOR**

CFR(s): 493.1403

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.

This CONDITION is not met as evidenced by:

The laboratory director failed to ensure Laboratory A and Laboratory B did not share proficiency testing (PT) complete blood count (CBC) samples prior to the result due date (Refer to D6004); and failed to ensure notification to HHS within 6 months of addition of the Hematology specialty (Refer to D6004).

## LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(a)(b)

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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

CITATION NUMBER ONE: Based on observation of the laboratory, review of the proficiency testing (PT) records, interview with Laboratory A testing personnel number one and the American Proficiency Testing customer service, the laboratory director (for Laboratory A and Laboratory B) failed to ensure the technical consultant (for Laboratory A and Laboratory B) did not send an internal courier to Laboratory A, collect the 2017 event 3 proficiency testing (PT) CBC samples and bring the PT samples to Laboratory B prior to the result due date, in 2017. The findings include: 1) Observation of Laboratory A on March 23, 2018 at 1:58 pm revealed the Sysmex XP-300 (serial number B1821) CBC instrument in use for patient testing. 2) Review of the 2017 event three API PT records and CBC instrument printout records revealed testing Laboratory A personnel number one performed PT CBC sample testing on November 20, 2017 for sample numbers HSY11, HSY12, HSY13, HSY14, and HSY15. Laboratory A CBC instrument results were submitted to API on November 20, 2017. 3) Interview on March 23, 2018 at 2:00 pm with Laboratory A testing personnel number one confirmed that on November 27, 2017, the (sister lab) Laboratory B testing personnel called Laboratory A stating the technical consultant for both Laboratory A and B, was sending an internal courier to collect the 2017 event three PT CBC samples and transport them to Laboratory B, located approximately 23 miles/28 minutes away. Laboratory A testing personnel number one did not want to send the PT CBC samples to Laboratory B, but felt intimidated since the courier was in route and the technical consultant requested the 2017 event 3 PT CBC samples for Laboratory B. She confirmed Laboratory A reported their own CBC PT results to API on November 20, 2017. 4) Interview with API customer service on March 28, 2018 at 10:06 am confirmed the PT 2017 event 3 result due date was December 1, 2017.

CITATION NUMBER TWO: Based on observation of the laboratory, review of the proficiency testing (PT) records, the CLIA notification requirements, and interview with Laboratory A testing personnel number one, the laboratory director failed to ensure notification to HHS within 6 months of addition of the Hematology specialty, in 2017. The findings include: 1) Observation of Laboratory A on March 23, 2018 at 1:58 pm revealed the Sysmex XP-300 instrument (serial number B1821) in use for patient testing. 2) Review of the 2017 event 3 PT records revealed participation with the Sysmex XP-300 instrument for CBC testing. 3) The 493.51 Notification requirements for laboratories issued a certificate of compliance. Laboratories issued a certificate of compliance must meet the following conditions: (b) Notify HHS (Health and Human Services) no later than 6 months after performing any test or examination within a specialty or subspecialty area that is not included on the laboratory's certificate of compliance, so that compliance with requirements can be determined. 4) Interview on March 28, 2018 at 1:36 pm with Laboratory A testing personnel number

one confirmed complete blood count (CBC) patient testing began August 8, 2017 and no notification to HHS was given for addition of the Hematology specialty.