

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2092054	(X3) Date Survey Completed 11/15/2018
Name of Provider or Supplier College Recovery Llc	Street Address, City, State 104 Bayard Street, New Brunswick, 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
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing records and interview with the Testing Personnel (TP), the laboratory failed to evaluate coded results obtained for Urine Drug proficiency testing event performed with the American Proficiency Institute. The findings include: 1. The laboratory did not evaluate 'Not Graded' grade achieved for event 3 of 2016 sample #s UAD 05 and 06. 2. The TP confirmed on 11/15 /18 at 1:00 pm that the laboratory failed to evaluate coded results.</p>
D5805	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Final Reports (FR) and interview with the Testing Personnel (TP), the laboratory failed to ensure that Urine Drug tests FR had accurate</p>

	<p>information from 2/21/17 to the date of survey. The finding includes: 1. The laboratory reported units of measurements with qualitative urine drug results. 2. The laboratory did not report cut-off values for urine drug tests. 3. The TP confirmed on 11/15/18 at 12:45 pm that the FR did not include accurate information.</p>
<p>D5807</p>	<p>TEST REPORT CFR(s): 493.1291(d)</p> <p>Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of Final Reports (FR) and interview with the Testing Personnel (TP), the laboratory failed to report Reference Range (RR) for all Urine Drug tests from 2/21/17 to the date of survey. The TP confirmed on 11/15/18 at 1:15 pm that RR was not on the FR.</p>
<p>D6018</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii)</p> <p>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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to ensure that all PT results received from American Proficiency Institute were reviewed by the appropriate staff for 2016, 2017 and 2018 events. The finding includes: 1. PT event 3-16, Performance Evaluation (PE) stated "All results acceptable" but the laboratory did not ensure Creatinine UAD 05 and 06 results were acceptable. 2. The laboratory did not retain PE records for PT events 2-17 and 1-18. 3. The TP confirmed on 11/15/18 at 1:30 pm that the PT results were not reviewed and retained.</p>