

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2092054	(X3) Date Survey Completed 10/19/2021
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
D0000	The survey conducted on October 19, 2021 found the laboratory in compliance with 42 CFR part 493 Requirements for Laboratories.
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation of the Quality Control (QC) material and interview with the Testing Personnel (TP), the laboratory had expired QC material for Toxicology tests run on the AMS Liasys 450 from 7/24/21 to the date of the survey. The findings include: 1. Reagents were expired as follows: a. AMS Ecstasy Control 1 & 2 Lot 206081 expired 7/24/21 b. AMS Opiate Control 1& 2 Lot 196111 expired 8/9/21 2. Approximately 30 patients per week were run and reported. 3. The TP confirmed on 10/19/21 at 1:50 am that the laboratory used expired QC.</p>
D5439	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test</p>

system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by: