Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	30D2116758	05/18/2018
Name of Provider or Supplier	**Street Address, City, State**	
Riverbend Community Mental Health, Inc	42 Pleasant St, Concord, NH	

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
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) 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 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: Based on record review and staff interview, the laboratory failed to verify calibration verification for urine creatinine tests in 2017 and 2018. Findings include: 1) Review on 5/18/18 of two final reports from May 2018 revealed urine creatinine was reported quantitatively. 2) Review on 5/18/18 of urine creatinine calibration verification reports dated 3/8/2017, 8/24/2017, and 4/30/2018 revealed the laboratory used "Validate UC 4 Calibration Verification /Linearity Test Kit" (Validate) materials for

	calibration verification. The laboratory did not evaluate its calibration verification results with peer data or expected values obtained through alternate means. 3) Review on 5/18/18 of the package insert for Validate revealed the materials included in the kit did not have expected or target values. 4) Interview on 5/18/18 at 9:30 a.m. with testing personnel confirmed urine creatinine was reported quantitatively and revealed the laboratory did not obtain peer data from the Validate manufacturer and did not evaluate the urine creatinine calibration verification results with expected values.