Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 15D2119413	(X3) Date Survey Completed 10/01/2018
Name of Provider or Supplier Community Healthcare Consultants Llc Dba Community	**Street Address, City, State** 2916 Peach Blossom Dr, Ste 101, Jeffersonville, IN	

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 reviews and interview, the laboratory failed to perform calibration verification every six months for three (cholesterol, glucose, and triglycerides) of three tests in the specialty of Routine Chemistry. Finding(s) include: 1. The policy, Calibration/Calibration Verification, approved 12/07/17, in the SOP (Standard Operating Procedures) manual read: "Calibration verification is necessary to verify

	that an analyte's calibration has remained valid, and confirms that patient testing provides continued accurate results throughout the previously established reportable range. Calibration verification is performed every six months..." 2. Review of calibration verification documents indicated the last calibration verification performed for cholesterol, glucose, and triglycerides was on 12/17. 3. The laboratory reported the following patients volumes during July (107), August (131), and September (103) in 2018. The following patients had been reported without calibration verification: ID # Date Test Value (2018) Cholesterol mg/dL 11 9/05 157 14 7/26 169 17 8/16 136 Glucose 10 9/25 97 13 7/12 171 ID # Date Test Value Glucose 16 8/09 117 Triglycerides 12 8/27 344 15 7/13 96 18 8/21 154 4. On 10/01/18 at 9:50 a.m., staff member #1 confirmed the last calibration verification for cholesterol, glucose, and triglycerides was documented on 12/17. The next calibration verification was due on 6 /18, but was not performed.