

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  26D0447478	<b>(X3) Date Survey Completed</b>  04/17/2019
<b>Name of Provider or Supplier</b>  Burton Creek Rural Clinic	<b>Street Address, City, State</b>  805 Kentucky Street, West Plains, MO	
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>D5401</b>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on review of Vitros 350 chemistry procedure and interview with testing personnel #1 the laboratory failed to follow chemistry quality control (QC) procedure two of forty two chemistry testing days in February and March 2019. Findings: 1. Review of chemistry QC procedure states 3 levels of QC will be performed every day of patient testing. On March 8, 2019 only 2 levels of chemistry QC was performed. 2. On February 26, 2019, two levels of sodium QC, potassium QC and chloride QC was performed. 3. Interview with testing personnel #1 on April 17, 2019 at 12:10 PM confirmed the laboratory failed to follow chemistry QC procedure.</p>
<b>D5439</b>	<p><b>CALIBRATION AND CALIBRATION VERIFICATION</b> 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 system; and (b)(3) At least once every 6 months and whenever any of the following</p>

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 review of calibration records for the Vitros 350 chemistry analyzer and interview with testing personnel #1, the laboratory failed to perform calibration verification procedures at least once every six months that included at least a minimal value, a mid-point value and a maximum value near the upper limit to verify the laboratory's reportable range for 19 of 19 analytes in 2018. Findings: 1. Review of the calibration records for 2018 for the analytes: glucose, blood urea nitrogen, creatinine, total protein, total bilirubin, direct bilirubin, albumin, AST, ALT, alkaline phosphatase, calcium, sodium, potassium, chloride, CO2, cholesterol, triglycerides and HDL showed the laboratory did not perform calibration every six months. 2. Interview with testing personnel #1 on April 17, 2019 at 12:10 PM confirmed the laboratory failed to perform calibration verification for chemistry analytes at least once every six months.

**D5447**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(d)(3)(i)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:  
Based on review of TSH quality control (QC) and interview with testing personnel #1 on April 17, 2019 at 12:10 PM confirmed the laboratory failed to perform two control materials of different concentrations each day of patient testing for TSH in 2017, 2018 and to date April 17, 2019.