

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0405733	(X3) Date Survey Completed 11/21/2018
Name of Provider or Supplier Centracare Laboratory Services-Urology	Street Address, City, State 2351 Connecticut Ave S Suite 200, Sartell, MN	
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	<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 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.</p> <p>This STANDARD is not met as evidenced by: . Based on observation, document review and interview with laboratory personnel, the laboratory failed to perform calibration verification on two chemistry analyzers at least every 6 months. Findings are as follows: 1. The laboratory performed chemistry testing as confirmed by the Technical Consultant (TC) during a tour of the laboratory on 11/21/18 at 8:10 a.m. 2. Three Qualigen FastPack IP System chemistry analyzers were observed as present and available for use during the tour of the laboratory. 3.</p>

Calibration verification was required every 6 months as indicated in the Total PSA procedure located in the Adult and Pediatric Urology procedure manual. 3. The 6 month calibration verification (cal.) interval for analyzer #0791 and analyzer #1142 was exceeded on one occasion in the time period reviewed; February 2017 through date of survey, 11/21/18. See below. Qualigen FastPack IP System #0791 Previous cal. Subsequent cal. Time elapsed 10/20/17 10/30/18 12 mo., 11 days Qualigen FastPack IP System #1142 Previous cal. Subsequent cal. Time elapsed 12/04/17 10/30/18 10 mo., 27 days 4. In an interview on 11/21/18 at 11:00 a.m., the TC confirmed the 6 month calibration verification interval had been exceeded for the two analyzers..