

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D2036695	<b>(X3) Date Survey Completed</b>  02/15/2018
<b>Name of Provider or Supplier</b>  Ochsner Choctaw General	<b>Street Address, City, State</b>  401 Vanity Fair Lane, Butler, AL	
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>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 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 a review of the Vitros 350 Chemistry analyzer calibration verification records and an interview with the laboratory manager, the laboratory failed to perform a calibration verification for Sodium (Na), Potassium (K), and Chloride (Cl) every six months in 2017. This affected one of three calibration verification performed. The findings include: 1. A review of the calibration records revealed a missing calibration verification for Na, K, and Cl in 2017: a calibration verification was performed on 3</p>

/10/2016, 9/28/2016 and not again until 9/18/2017,exceeding the every six month timeframe. The analytes listed only have two routine calibrators. 2. Whenever any analyte is calibrated with less than three calibration points, a calibration verification is required every six months. 3. During an interview on 2/15/2018 at 2:35 PM, the laboratory manager was asked if she had records for the calibration verification. The laboratory manager stated she did perform the calibration verification but could not find the records during the survey. Jeremy Westry, BS, MT (ASCP) Licensure and Certification Surveyor