

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  39D2109944	<b>(X3) Date Survey Completed</b>  07/13/2018
<b>Name of Provider or Supplier</b>  Dsp Health System	<b>Street Address, City, State</b>  230 Independence Road, East Stroudsburg, PA	
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 review of Beckman Coulter AU 480 Chemistry Analyzer calibration records and interview with testing personnel (TP) #1, the laboratory failed to perform calibration verification (CV) on the Beckman Coulter AU 480 at least every 6 months in 2018. Findings include: 1. On the day of survey, 07/13/2018, review of Beckman Coulter AU 480 CV records, revealed that the laboratory did not perform CV at least every six months. The last CV was performed on 12/18/2018 and was due to be</p>

performed on 06/18/2018. 2. In 2017: 148 Chemistry tests were analyzed. 3. TP #1 confirmed the finding above on 07/13/2018 around 10:30 am.