

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2090945	(X3) Date Survey Completed 08/11/2021
Name of Provider or Supplier Geisinger Wyoming Valley Poct	Street Address, City, State 1000 East Mountain Boulevard, Wilkes Barre, PA	
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 calibration verification records and interview with the technical consultant (TC) #2, the laboratory failed to perform as required calibration verification on 20 of 21 Abbott i stat systems used for chemistry point of care (POC) testing from 2019 to the date of survey. Findings Include: 1. On the day of survey, 08/11/2021, a review of calibration verification records revealed, the laboratory had 21 Abbott i stat systems and performed calibration verification on 1 Abbott i stat system every 6 months. 2.</p>

The laboratory did not perform the required calibration verification on 20 of 21 Abbott i stat systems used for chemistry point of care (POC) testing from 08/11/2019 to 08/11/2021. 3. TC #2 confirmed the findings above on 08/11/2021 around 01:00 pm.