

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0953969	(X3) Date Survey Completed 12/09/2020
Name of Provider or Supplier Patient First - Cedar Road	Street Address, City, State 1239 Cedar Road, Chesapeake, VA	
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
D0000	An announced virtual CLIA recertification survey was conducted for Patient First-Cedar Road on December 9, 2020 by the Virginia Department of Health's Office of Licensure and Certification. The survey included an entrance interview on 12/2/2020 and initial record review conducted on 12/7/2020. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiency cited is as follows:
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:</p>

Based on a review of the laboratory's procedures, calibration verification records for the Abbott point of care chemistry analyzer, lack of documentation, and an interview, the laboratory failed to follow their six (6) month calibration verification protocol for eight (8) of 8 chemistry analytes in calendar year 2020. Findings include: 1. Review of procedures revealed a policy to perform calibration verification with a minimal (or zero) value, a mid-point value, and a maximum value once every six months. The inspector inquired of the policy for the iSTAT analyzer and the laboratory technical consultant (TC) stated on 12/9/20 at approximately 12:30 PM, "We perform a cal ver every six months for the Chem8 now that is is not a waived test, to verify that it is accurate to the reportable range". 2. Review of the laboratory's 2020 calibration verification records for Sodium (Na), Potassium (K), Chloride (Cl), TCO₂, Ionized Calcium (iCa), Glucose (Glu), Urea Nitrogen (BUN)/Urea, and Creatinine (Creat) reported on the iSTAT analyzer (Serial Number 307629), revealed the following documentation: 02/21/20 Calibration Validation to establish reportable range studies performed and accepted by TC and lab director; 11/23/20 Calibration Verification performed and accepted by testing personnel and TC The inspector requested to review documentation of calibration verification performed in August 2020 for Na, K, Cl, TCO₂, iCa, Glu, BUN, and Creat on the iSTAT. The documentation was not available for review. The Senior Laboratory Consultant stated at approximately 1:30 PM, "It appears that the previous supervisor did not follow the protocol for completing the Cal Ver report form with three QC values at the six months." 3. In an interview with the TC and Senior Laboratory Consultant on 12/9/20 at approximately 1:30 PM, the above findings were confirmed.