

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 49D0665312	<b>(X3) Date Survey Completed</b> 10/13/2021
<b>Name of Provider or Supplier</b> Patient First - Indian River	<b>Street Address, City, State</b> 5486 Indian River Rd, Virginia Beach, VA	
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>D0000</b>	An announced virtual CLIA recertification survey was conducted for Patient First-Indian River on October 13, 2021 by the Virginia Department of Health's Office of Licensure and Certification. The survey included a remote entrance interview and initial record review conducted on 10/12/21. The inspector noted that the laboratory performs SARS-CoV-2 (COVID-19) testing and was in compliance with the applicable COVID-19 reporting requirements. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiency cited is as follows:
<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>

This STANDARD is not met as evidenced by:

Based on a review of procedures, calibration verification records for the Abbott point of care chemistry analyzer, and interviews, the laboratory failed to follow their six (6) month calibration verification protocols for eight (8) of 8 chemistry analytes during the twenty-four (24) months reviewed. Findings include: 1. Review of procedures revealed a policy to perform calibration verification once every 6 months. The inspector inquired of the policy for the iSTAT analyzer and the laboratory technical consultant (TC) stated on 10/13/21 at approximately 11:30 AM, "We do cal verification every six months for the Chem8 to verify reportable range accuracy." 2. Review of the laboratory's calibration verification records (timeframe of October 2019 to October 2021) for Sodium (Na), Potassium (K), Chloride (Cl), TCO<sub>2</sub>, Ionized Calcium (iCa), Glucose (Glu), Urea Nitrogen (BUN)/Urea, and Creatinine (Creat) reported on the iSTAT analyzer (Serial Number 337043), revealed the following documentation: 02/21/20 Calibration Validation to establish reportable range studies performed and accepted by TC and lab director; 08/10/20 Calibration Verification performed and accepted by testing personnel and TC; 06/04/21 Calibration Verification performed and accepted by testing personnel and supervisor. The inspector requested to review documentation of calibration verification performed in the timeframe of February 2021 for Na, K, Cl, TCO<sub>2</sub>, iCa, Glu, BUN, and Creat on the iSTAT. The documentation was not available for review. The Director of Laboratory Services stated at approximately 12:30 PM: "We are in the process of updating our procedures because our supervisors were previously familiar with performing the iSTAT calibration verification at each time of Abbott's periodic software updates. Those updates do not always coincide with the 6 month cal verification due date. A newly worded procedure should eliminate confusion on the six month requirement". 3. An interview with the TC and Director of Laboratory Services on 10/13/21 at approximately 1:30 PM, confirmed the above findings.