

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0961491	(X3) Date Survey Completed 03/09/2022
Name of Provider or Supplier Chickahominy Family Practice- Central Lab	Street Address, City, State 9010 Pocahontas Trail, Providence Forge, 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 CLIA Recertification survey was conducted at the Chickahominy Family Practice-Central Lab on 03/09/22 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are 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: **REPEAT DEFICIENCY** Based on the review of policy and procedures (P&P),</p>

manufacturer's user manual, calibration verification records, lack of documentation and interview, the lab failed to follow the established P&P of performing calibration verification procedures twice a year for the Tosoh G8 A1C analyzer in 2020. Findings include: 1. Review of the P&P revealed the following statement, "Tosoh G8 Analyzer- Calibration verification is done twice a year and recorded." 2. Review of the manufacturer's user manual revealed the Tosoh G8 A1C analyte has a two-point calibration. 3. Review of calibration verification records for 2020 and 2021 revealed lack of documentation for the performance of calibration verification procedures twice a year in 2020. The inspector reviewed the documents for procedures performed on 10/23/19 and 11/04/20. The inspector requested to review additional calibration verification procedures for the calendar year 2020. No additional documents were available for review. 4. An exit interview with the technical consultant and primary testing personnel on 03/09/22 at approximately 1210 confirmed the findings.