Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2176072	03/09/2023
Name of Provider or Supplier	**Street Address, City, State**	
Uva Medical Center Medical Laboratories	1215 Lee Street, Charlottesville, 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 validation survey was conducted at UVA Medical Center Laboratories -Point of Care Testing on March 8-9, 2023 by the Virginia Department of Health's Office of Licensure and Certification. 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 Requirements. Specific deficiency cited is as follows:
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) 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.

	This STANDARD is not met as evidenced by: Based on a review of procedures, point of care (POC) analytical measurement range (AMR) calibration verification records, lack of documentation, and interviews, the laboratory failed to follow their procedure to perform calibration verification every six months on Abbott EG7+ reagent cartridges for Potassium (K), Sodium (Na), Ionized Calcium (Ca), Total Hemoglobin (tHb), Hematocrit (Hct), Hydrogen Ion Concentration (pH), Carbon Dioxide Partial Pressure (PCO2), and Oxygen Partial Pressure (PO2) on four (4) of 4 Abbott iSTAT instruments, Sweat Chloride on two (2) of 2 ChloroChek Chloridometer analyzers, and tHb Concentration and Oxyhemoglobin fraction (HbO2%) on 7 of 7 Werfen Avoximeter analyzers during a twenty-four month review timeframe of calendar year 2021 to the dates of the validation survey March 8-9, 2023. Findings include: 1. Review of the laboratory's POC procedures revealed a chemistry and oximetry calibration verification protocol (titled: POC AMR Verification) which stated, "The following analyzers require AMR verification within the Point of Care Testing Program: Rapid Point 500 E, Avoximeter 1000E, iSTAT (EG7+ cartridges), and Chorochek Sweat Chloride. The frequency for all analytes is every six months, every analyzer." The inspector noted the procedure was approved by the lab director (LD) on 2/5/15 and again on 10/11/22. 2. Review of the laboratory's POC calibration verification documentation during the timeframe of 2021 to the dates of the inspection 03/08 - 03/09/23, revealed the following of calibration verification records: Abbott iSTAT EG7+ (K, Na, Ca, tHb, Hct, pH, PCO2, PO2) - February and August 2021, February and October 2022 for analyzer serial numbers (SNs) 370312, 331816, 383707, 386457; ChloroChek Chloridometer (Sweat Chloride) - January and July 2021, January and September 2022 for SNs 3400190641, 340016045; Werfen Avoximeter (tHb, HbO2%) - December 2021 and September 2022 for SNs 2718, 2550, 2544, 2716, 7681, 7680, 6215. The inspector noted the following lapses in documentation of AMR at every six (6) month intervals during the review timeframes outlined above: Abbott iSTAT EG7+ - 4 analyzers had a two month lapse for eight (8) of 8 analytes as outlined above in 2022; Chlorochek Sweat Chloride - 2 analyzers had a three month lapse for one (1) of 1 analyte in 2022; Werfen Avoximeter (tHb, HbO2%) - 7 analyzers had a six month lapse in 2021 and four month lapse in 2022 for two (2) of 2 analytes. h 3. The inspector requested to review additional documentation of every six month calibration verification for the eleven (11) analytes assayed on the thirteen (13) chemistry/oximetry instruments outlined above. No records were available. 4. Interviews with the Laboratory Administrator, Quality and Safety Coordinator, Director of Point-of-Care Testing and Phlebotomy, and the Point of Care Medical Director on 3/8/23 at approximately 2:45 PM and an exit interview with the Director of Point-of-Care Testing and Phlebotomy on 3/9/23 at approximately 1:00 PM confirmed the above findings.