

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0865334	(X3) Date Survey Completed 10/13/2022
Name of Provider or Supplier Valdosta State University- Student Health Center	Street Address, City, State 200 Georgia Avenue, Valdosta, GA	
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	<p>A recertification survey was performed on October 13, 2022. An entrance conference was held with the laboratory representatives. The survey process was discussed, along with review of the survey forms that was sent to the facility, previous to the survey. An opportunity for questions and comments was given. Noted deficiencies and plans of correction were discussed with the laboratory representatives at the exit conference. The laboratory representatives were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided. The facility was found NOT to be in compliance with all applicable CLIA requirements for specialties/subspecialties for 42 CFR. 493.1255(b) Calibration and Calibration Verification procedures 493.1407(e)(3)(ii) Laboratory Directors Responsibilities NOTE: The CMS-2567 (Statement of Deficiencies) is an official , legal document,. All information must remain unchanged except for entering the Plan Of Correction (POC), correction dates, and the signature space. Any discrepancy n the original deficiency citation(s) will be reported the the Georgia Regional Office (RO) for referral the Office of the Inspector General (OIG) for possible fraud if the information is inadvertently changed by the provide/supplier, the State Survey Agency (SA) should be notified immediately.</p>
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</p>

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 review of the Beckman/Coulter LHx 520 (LHx), and staff interview, the laboratory failed to perform calibration at least every 6 months, from June 3, 2021 to September 7, 2022. 493.1255(b)(3) Findings: 1. A review of the calibration documents for the LHx Hematology Analyzer for the years 2021 and 2022 revealed calibration on dates June 3, 2021 and September 7, 2022, a 15 month time span. 2. Interview with staff #1 (CMS form 209) and the Laboratory Director on October 13, 2022 at approximately 1pm, in the facility manager's office, confirmed that the laboratory failed to document calibration between June 3, 2021 and September 7, 2022.

D6013

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(3)(ii)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;

This STANDARD is not met as evidenced by:
Based on review of the Beckman/Coulter LHx(LHx) calibration documents, and staff interview, the Laboratory Director(LD), failed to ensure that the laboratory was performing calibrations every 6 months, as required in 493.1255(b)(3). [493.1407(e)(3)(ii)] Findings: 1. Review of the LHx calibration documents for the years 2021 and 2022 revealed calibrations were completed on June 3, 2021 and September 7, 2022, a period of 15 months between calibrations. 2. Interview with staff#1 (CMS-209) , and the LD, on 10/13/2022, at approximately 1pm, in the manager's office, confirmed that the laboratory failed to document calibrations between June 3, 2021 and September 7, 2022.