Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0920876	08/10/2022
Name of Provider or Supplier	**Street Address, City, State**	
Georgia College & State University	134 West Campus Drive, Milledgeville, 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	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on August 10, 2022. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of profiency test (PT) records and staff interview, the laboratory director/designee failed to attest that PT samples were tested in the same manner as patient specimens. Findings include: 1. Review of PT documents of 2020 event #3, 2021 events #1, 2, 3, and 2022 event #1 revealed the lab director/designee failed to attest that PT samples were tested in the same manner as patient specimens for 2021 events # 2 and #3. 2. Interview with staff #2 (CMS 209) on 08/10/22 at approximately 11:30 A.M in the main lab confirmed the lack of the aforementioned signatures on the attest statements.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by:

	Based on review of proficiency testing (PT) documents and staff interview the lab failed to retain records of results received from the PT provider in order to review and evaluate the results obtained. Findings include: 1. Review of PT documents of 2020 event #3, 2021 events #1, 2, 3, and 2022 event #1 revealed the lab failed to have result records for 2020 event #3, and 2021 event #1. 2. Interview with staff #2 (CMS 209) on 08/10/22 at approximately 11:30 A.M in the main lab confirmed the lack of the aforementioned PT result documents.
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 calibration document review and staff interview, the lab failed to calibrate the Cell-Dyn Emerald analyzer every six (6) months as required by the manufacturer. Findings include: 1. Review of calibration data revealed the Sysmex XP-300 was calibrated 08/19/20, 12/14/20, 11/11/21 (eleven month span), and 5/4/22. No calibration was performed in June 2021. 2. Interviews with staff #1 and #2 (CMS 209 form) on 08/10/22 at approximately 12 PM in the main lab, confirmed the lack of calibration for June 2021.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

	This STANDARD is not met as evidenced by: Based on review of profiency test (PT) records and staff interview, the laboratory director failed to document review of PT results. Findings include: 1. Review of PT documents of 2020 event #3, 2021 events #1, 2, 3, and 2022 event #1 revealed the lab director failed to document review of PT results for 2020 event # 3, 2021 events # 1 and #3, and 2022 event #1. 2. Interview with staff #2 (CMS 209) on 08/10/22 at approximately 11:30 A.M in the main lab confirmed the lack of the aforementioned signatures on the PT result documents.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on review of testing personnel (TP) documents and staff interview , the technical consultant failed to perform annual competency on all testing personnel. Findings include: 1. Review of personnel competency documents revealed the lack of documentation for annual reviews for the year of 2021. No 2021 documentation were available. 2. Interview with staff # 1 (CMS 209) on 8/10/22 in the main lab at 10:25 AM confirmed the 2021 competencies were not done.