Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 11D0920876	**(X3) Date Survey Completed** 10/20/2020
Name of Provider or Supplier Georgia College & State University	**Street Address, City, State** 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 October 20, 2020. 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:
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute, (API), evaluation reports for KOH Preps, and staff interview, the laboratory failed to verify the accuracy of the KOH preps twice annually. Findings: 1. Review of the API evaluation reports for KOH preps, the laboratory received unsuccessful scores for 2020 events 1 and 2. The laboratory did not verify the accuracy of the KOH preps twice annually over the last 12 months. 2. Interview with staff #3, (CMS 209), on October 20, 2020, at approximately 1pm in the break room, confirmed that the laboratory had not verified the accuracy of the KOH preps.
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 the American Proficiency Institute (API), and staff interview, the Laboratory Directory(LD) failed to document review and evaluation of the Proficiency scores. Findings: 1. Review of the API Evaluation Documents for Hematology and Wet Preps, from 2018 3rd event thru 2020 2nd event showed that only 2 out of the 11 events for Hematology and Wet Prep API evaluation reports were signed by the LD as being reviewed. For Hematology 2018 third event - review was not signed by LD 2019 first event - review was not signed by LD 2019 second event - review was not signed by LD 2019 third event - review was not signed by LD 2020 first event - review signed by LD For KOH: 2018 third event - review was not signed by LD 2019 first event - review was not signed by the LD 2019 second event - review was not signed by the LD 2019 third event - review was not signed by the LD 2020 first event - review was not signed by the LD 2020 second event - review was signed by the LD 2. Interview with staff # 3 (CMS 209) on 10/20/2020 at approximately 11: 30 am in the breakroom, confirmed the above aforementioned data review.