Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0706096	(X3) Date Survey Completed 02/26/2021
Name of Provider or Supplier Laurens County Health Department	**Street Address, City, State** 654 County Farm Road, Dublin, 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 February 26, 2021. 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:
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on review of the American Associates of Bioanalysts (AAB) Proficiency Testing (PT) documents, the laboratory failed to receive successful scores for Potassium Hydroxide Prep (KOH), and Wet Prep for the 2019, and 2020. The laboratory has 4 out of 5 unsuccessful scores of 0% for WET PREP for events two

	and three in 2019 and events two and three of 2020. The laboratory had 4 out of 5 unsuccessful scores of 0% for KOH for event three of 2019 and events one,two,and three of 2020. REFERENCE: D2039, D2048 1. Review of the AAB PT documents for 2019, Wet Prep, the laboratory scored 0% for event two and three, and in 2020 the laboratory scored 0% for events two and three. 2. Review of the AAB PT documents for 2019, KOH, the laboratory scored 0% for event three. The laboratory scored 0% for events one, two, and three in year 2020. 3. The Assistant Nursing Director, confirmed by an email , dated 3/5/2021, samples were not tested or submitted, but were reviewed by all nursing staff. There was no documentation supporting the results of the nursing staff review and no documentation of the correct identification of the samples. The Assistant Nursing Director confirmed by email that results were not submitted for grading due to the pandemic. The Assistant Nursing Director also confirmed, that the laboratory continued seeing patients and patient testing continued onsite during the pandemic.
D2039	MYCOLOGY CFR(s): 493.827(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3)The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on review of American Associates of Bioanalysts (AAB) Proficiency Testing (PT) documents, in the Microscopy speciality, the laboratory failed to participate in the third event of 2019, as well as the first, second, and third events of 2020 for Potassium Hyroxide (KOH). Findings: 1. Review of the AAB, PT documents for KOH skin prep, the laboratory failed to submit samples for scoring for the third event of 2019, as well as the first, second, and third event of 2020. 2. The Assistant Nursing Director, confirmed by an email dated 3/5/2021, PT samples were not tested or submitted but were reviewed by all nursing staff. There was no documentation supporting the results of the nursing staff review and no documentation of the correct indentification of the samples. The Assistant Nursing Director confirmed by email that results were not submitted for grading due to the pandemic. The Assistant Nursing Director confirmed by email that patients were seen and patient testing continued onsite during the pandemic.
D2047	PARASITOLOGY CFR(s): 493.829(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on review of the American Associated of Bioanalysts (AAB) Proficiency

	Testing (PT) documents, the laboratory failed to attain an overall testing event score of at least 80 percent for Microscopy (Wet Prep) for the second event in 2019. Findings: 1. Review of the AAB PT documents for 2019 (Wet Prep), the laboratory recieved a score of 0% for the second event. 2. Inteview with the Assistant Nursing Director, by an email dated 3/3/2021, at 10:58 pm, confirmed the laboratory did not receive a score of at least 80% for Wet Prep, AAB PT, second event, for year 2019.
D2048	PARASITOLOGY CFR(s): 493.829(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on review of the American Associates of Bioanalysts (AAB) Proficiency Testing (PT) documents for Microscopy, the laboratory failed to participate in the third event of 2019, as well as the second and third events of 2020 for Wet Prep. Findings: 1. Review of the AAB, PT documents for Wet Prep, the laboratory failed to submit samples for scoring for the third event of 2019, as well as the second and third event of 2020. 2. The Assistant Nursing Director, confirmed by an email dated 3/5 /2021, that the sampes were not tested or submitted, but were reviewed by all nursing staff. There was no documentation supporting the results of the nursing staff review and no documentation of the correct indentification of the samples. The Assistant Nursing Director confirmed that PT samples were not submitted for grading due to the Pandemic. The Assistant Nursing Director also confirmed pateints were seen and testing performed onsite during the pandemic.
D6041	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(3) (b) The technical consultant is responsible for-- (b)(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered; This STANDARD is not met as evidenced by: Based on review of the American Associates of Bioanalysts (AAB) Proficiency Testing (PT) documents, the Technical Consultant(TC) failed to monitor and review the PT testing and scores for the test menu performed at the facilities. The laboratory received unsuccessful scores for Potassium Hydroxide Prep (KOH), and Wet Prep for the 2019, and 2020 testing year. The laboratory has 4 out of 5 unsuccessful scores of 0% for WET PREP for events two and three in 2019 and events two and three of 2020. The laboratory had 4 out of 5 unsuccessful scores of 0% for KOH for event three of 2019 and events one,two,and three of 2020. 1. Review of the AAB PT documents for 2019, Wet Prep, the laboratory scored 0% for event two and three, and

	in 2020 the laboratory scored 0% for events two and three. 2. Review of the AAB PT documents for 2019, KOH, the laboratory scored 0% for event three. The laboratory scored 0% for events one, two, and three in year 2020. 3. The Assistant Nursing Director, confirmed by an email , dated 3/5/2021, samples were not tested or submitted, but were reviewed by all nursing staff. There was no documentation supporting the results of the nursing staff review and no documentation of the correct identification of the samples. The Assistant Nursing Director confirmed by email that results were not submitted for grading due to the pandemic. The Assistant Nursing Director also confirmed, that the laboratory continued seeing patients and patient testing continued during the pandemic.