Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 11D0669299	**(X3) Date Survey Completed** 03/11/2021
Name of Provider or Supplier Cobb & Douglas Public Health	**Street Address, City, State** 1650 County Services Parkway, Marietta, 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 March 11, 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:
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory policy and procedure manual (SOP) and staff interview, the laboratory failed to have a written policies and procedure for all tests performed by the laboratory as required. Findings include: 1. SOP review revealed the lack of a policy and procedure for quality control (QC) for KOH (Potassium Hydroxide) and Wet Prep (Wet Preparation) testing. 2. An interview in the conference room with Staff #11 (CMS 209 for Marietta Center Clinic) on 3/11/2021 at approximately 12:15 p.m. confirmed the lack of the aforementioned QC policy and procedure.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g)

	The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on laboratory document review and staff interview, the laboratory failed to document all quality control (QC) procedures as required. Findings include: 1. Laboratory document review revealed the lack of QC documentation for KOH (Potassium Hydroxide) and Wet Prep (Wet Preparation) for all 4 clinics -- Marietta Center, Acworth-Kennesaw, Smyrna, and Douglas -- for the following time periods: 2018 -- July through December;2019, 2020, and 2021 thus far. 2. An interview with Staff #11 (CMS 209 for Marietta Center Clinic) on 3/11/1021 in the conference room at approximately 11:30 p.m. confirmed the lack of QC for KOH and Wet Prep for the aformentioned time periods.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on lab report reviews and staff interview, the laboratory failed to include all the required information on the in-house laboratory test reports. Findings include: 1. Review of the in-house patient reports #193506, #260969, and #1129489 reveals the lack of referance range, units of measurement, and the health department's address where the test was performed. 2. Interview with Staff #11 (CMS 209 for Marietta Center Clinic) in the conference room on March 11, 2021, at approximately 1:30 p.m. confirmed the lack of the aforementioned data.