Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D2025053	11/09/2021
Name of Provider or Supplier	**Street Address, City, State**	
Columbus Womens Health Org	3850 Rosemont Drive, Columbus, 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 November 09, 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:
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) Proficiency Testing (PT) supplier documents, and staff interview, the laboratory was not rotating PT sample testing through the entire TP staff. Findings 1. Review of the API, PT attestation statements for the year 2020 and 2021, were signed by the same TP for all three events of 2020, and event one and two of 2021. 2. Staff interview with the laboratory manager, on 11/09/2021 at approximately 1 pm in the front office comfirmed the above aforementioned statement.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel

	meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) Proficiency Testing (PT) supplier documents, and staff interview, the Laboratory Director (LD) was not monitoring the PT sample testing was being rotated through the entire TP staff. Findings: 1. Review of the API PT attestation documents for all three events in 2020, and events one and two in 2021 showed that only one TP was performing the PT samples for evaluation. 2. Staff interview with the laboratory manager, on 11/09/2021 at approximately 1 pm in the front office comfirmed the above aforementioned statement.