

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0965359	(X3) Date Survey Completed 12/26/2019
Name of Provider or Supplier Columbus Center For Reproductive	Street Address, City, State 2323 Whittlesey Road, 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 December 26, 2019. 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:
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on review of the 2018 and 2019 maintenance schedules for the TOSOH AIA-900 chemistry analyzer(TOSOH), and staff interview, the laboratory failed to document Quarterly and Monthly Maintenance as required by the manufacturer. Findings: 1. Review of the maintenance schedules for the TOSOH showed that the laboratory did not document quarterly maintenance for five months in 2018, and monthly maintenance for one month in 2018. In 2019 the laboratory failed to document monthly maintenance for two months and one month no maintenance was marked. Also confirmed that the laboratory switched back to the TOSOH AIA-600 maintenance schedule in May of 2018. January through April 2018, quarterly maintenance was not marked as being completed May 2018 switched back to TOSOH AIA-600 maintenance schedule November 2018, monthly maintenance was not marked as being completed February and March 2019, monthly maintenance was not marked as being completed April 2019, no maintenance was marked as being completed 2. Interview with the TC, and staff #3 (CMS 209 form) on December 26, 2019, at approximately 1 pm, in exam room 1, confirmed that the maintenance was not marked as being performed as stated above.</p>