

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0674629	(X3) Date Survey Completed 12/20/2018
Name of Provider or Supplier Columbus Health Department	Street Address, City, State 5601 Veteran'S Parkway, 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 20, 2018. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following Condition was cited:
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on review of the American Associates of Bioanalysts (AAB) Proficiency Testing (PT) documents for 2018, and staff interview, the laboratory failed to enroll in PT testing for 1st and 2nd Events of 2018 for Gynecology (GYN) KOH Prep, and Wet Prep. Findings: 1. Review of the AAB PT documents for 2018, the laboratory did not enroll in PT testing for the 1st and 2nd events for GYN KOH Prep, and Wet Prep. The laboratory did enroll and received and submitted the data for the 3rd event of 2018. In 2017 the laboratory failed to perform PT testing for the 1st and 2nd events for 2017 for GYN KOH Prep and Wet Prep. 2. Interview with the Columbus Health Department District Nurse Manager, and the Columbus Health Department CLIA nurse coordinator, on December 20, 2018, at approximately 3 pm in the Talbot County Health Department conference room, confirmed that they had not participated in the 1st and 2nd events of PT in 2018 for GYN KOH Prep, and Wet Prep. They did</p>

enroll and participate in the 3rd event of 2018 for GYN KOH Prep, and Wet Prep.
Repeat Deficiency

D6015

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)

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) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.

This STANDARD is not met as evidenced by:

Based on review of the American Association of Bioanalysts (AAB) Proficiency Testing (PT) documents, and staff interview, the laboratory Director failed to ensure that the laboratory was enrolled in a CMS-Approved proficiency test program for Gynecology(GYN) KOH prep and Wet Prep for the First and Second events of 2018. Findings: 1. Review of the AAB PT documents the laboratory failed to enroll in a CMS-approved proficiency testing program for GYN KOH Prep and Wet Prep, for the first and second events of 2018. 2. Interview with the District Health Department Nurse Manager, and District Health Department CLIA nurse coordinator, on December 20, 2018 at approximately 3 pm, in the Talbot County Health Department conference room, confirmed that they were not enrolled in a PT program for the first and second event of 2018 for GYN KOH Prep and Wet Prep..