

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0866868	(X3) Date Survey Completed 02/15/2023
Name of Provider or Supplier Forsyth County Health Department	Street Address, City, State 428 Canton Highway, Cumming, 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	On March 26, 2023 an off site follow-up review was completed. The report revealed that the plan of correction was found to be acceptable. The facility is now in compliance with CLIA regulations.
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of Quality Control (QC), peer review documents, interviews with the Technical Consultant (TC) and nurse manager, the laboratory failed to prove that (QC) and KOH peer reviews were performed for Forsyth County Health Department in 2021 or 2022. Findings; 1. Documents review revealed, Potassium Hydroxide (KOH) wet preps for mycology and parasitology were NOT performed at least twice annually for Forsyth County HD in 2021 and 2022. 2. Quality Control (QC) document review revealed there was NO (QC) performed or daily verification against a Kodak Chrome to check testing accuracy when patient testing was performed in Forsyth County HD in 2021 or 2022. 3. The nurse manager and Technical Consultant (TC) (TP#2 CMS 209) in the conference room at approximately 12:30 PM on 02/15/2023 confirmed the laboratory had no proof of daily (QC) and KOH peer reviews were done twice annually for Forsyth County HD in 2021 and 2022.</p>
D6022	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>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</p>

and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on Quality Control (QC), KOH/ wet prep document review and staff interview, the Lab Director (LD) failed to ensure that proper Proficiency Testing (PT), QC and QA guidelines for non-regulated analyte were followed in Forsyth County Health Department in 2021 or 2022. Finding: 1. Daily Quality Control (QC), PT/KOH wet prep peer review documents revealed the laboratory director did not ensure that daily verifications against Kodak Chrome and Bi-annual KOH/ Wet prep peer reviews were performed as required in 2021 and 2022 in Forsyth County HD. 2. An interview with the nurse manager and (TC) (TP#2 CMS209) in the conference room on 02/15/2023 at approximately 12:30 PM, confirmed the LD did not ensure daily QC and KOH peer reviews were performed for the Forsyth County HD in 2020 to 2022.