Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0866868	03/10/2021
Name of Provider or Supplier	**Street Address, City, State**	
Forsyth County Health Department	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	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on March 15, 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:
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on the review of Proficiency Testing (PT) records and interviews with the nurse manager, the laboratory director failed to review and attest that PT samples were tested in the same manner as patient specimens. Findings include: 1. Review of the Medical Laboratory Evaluation(MLE) PT records revealed the laboratory failed to provide or retain the signed attestation forms for (MLE) PT events #s M2 of 2019 and M1 of 2020 in Forsyth County. 2. An interview with the nurse manager on 03/10/2021 at approximately 12:40 pm in the Forsyth County HD break room confirmed the PT documents were not reviewed and signed by the laboratory director.
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.

	This STANDARD is not met as evidenced by: Based on observation during the tour and an interview with the nurse manager, the laboratory failed to implement and established safety procedure to ensure protection from physical, biochemical, and biohazardous materials. Findings include: 1. During the laboratory tour it was observed there was no eyewash equipment installed or un-expired eyewash bottle or eyewash log in the phlebotomy or laboratory testing area in 2019, 2020. 2. An interview with the nurse manager during the tour on 03/10/2021 at approximately 10:30 a.m., confirmed the absence of eyewash equipment and maintenance log in 2019 and 2020.
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on Quality Assurance (QA) document review and an interview with the Nurse coordinator, the laboratory director failed to document all general laboratory systems QA activities as required. Findings include: 1. QA documents review revealed there were no consistent monthly or quarterly QA documentation available, reviewed and signed by the laboratory director who also acts as the Technical Consultant (TC) January to September 2019 and March to December 2020 for Forsyth county. 2. Room temperature logs, Humidity logs and refrigerator logs were not reviewed and signed by a (TC) or laboratory director on a consistent basis in 2019, 2020 and 2021 for Forsyth County. 3. An interview with the nurse coordinator in the break room on 03/10/2021 at approximately 12:30 p.m. confirmed lack of consistent QA oversight by the laboratory director for the aforementioned period.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on the Medical Laboratory Evaluation (MLE) proficiency test (PT) document review and interview with the nurse manager, the laboratory director(LD) failed to ensure that all PT reports were reviewed and signed as required. Findings include: 1. MLE (PT) document review revealed the LD failed to review and sign 2019 PT evaluation events: M2 and M3 KOH (Potassium Hydroxide) and Wet Prep for Forsyth

	County. 2. An interview with the County Nurse Manager on 03/10/2021 in the Forsyth County Health Department break room at approximately 12:35 p.m. confirmed the LD failed to review the aforementioned PT reports in 2019.