Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0697783	09/15/2020
Name of Provider or Supplier	**Street Address, City, State**	
Northeast Health District	220 Research Drive, Athens, 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	An Initial (Reinstatement) Clinical Laboratory Improvement Amendments (CLIA) survey was completed on September 15, 2020. The laboratory was not in compliance with all 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 proficiency test (PT) document review and staff interview, the laboratory director (LD) failed to attest to the routine integration of PT samples into the patient workload as required. Findings include: 1. American Association of Bioanalysts PT document review revealed the LD did not sign the attestation statement for the 2019 Clinical Microscopy (Event One) for KOH (Potassium Hydroxide) and Wet Prep (Preparation) testing. 2. An interview with the District Nursing and Clinical Director in a conference room on 9/15/2020 at approximately 4:45 p.m. confirmed the lack of LD signature for the aforementioned attestation statement.
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 maintenance document review and staff interview, the laboratory failed to document eyewash equipment maintenance as required. Findings include: 1. Maintenance document review revealed the following Health Department laboratories documented eyewash maintenance only one day in September, 2020: Clarke County (Main), Greene County, Jefferson County, Oconee County, and Walton County (Monroe). 2. Maintenance document review revealed there was no 2019 eyewash documentation available at the time of survey for the aforementioned laboratories. 3. Maintenance document review revealed there was no 2019 nor 2020 eyewash maintenance documentation available at the time of survey for the following Health Department laboratories: Barrow County, Clarke County (East), Jackson County, Elbert County,Walton County (Loganville), Madison County, Morgan County, Oglethorpe County, Clarke County (Cedar), Clarke County (Central), and Clarke County (Specialty Care Clinic). 4. An interview in a conference room with the District Nursing and Clinical Director on 9/15/2020 at approximately 4:00 p.m. confirmed the lack of eyewash maintenance documentation and limited eyewash documentation for the sixteen (16) aforementioned Health Department laboratories for 2019 and 2020.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on quality control (QC) document review and staff interview the laboratory failed to document QC for each day of patient testing as required.. Findings include: 1. QC document review revealed the following laboratories failed to document QC for KOH (Potassium Hydroxide) and Wet Prep(Preparation) testing: Clarke County(East) for 2019: Walton County (Loganville) for 2019 and 2020. 2. An interview in a conference room with the District Nursing and Clinical Director at approximately 4: 30 p.m. on 9/15/2020 confirmed the lack of KOH and Wet Prep QC documentation for 2019 and 2020.