Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0691469	03/09/2021
Name of Provider or Supplier	**Street Address, City, State**	
Hall County Health Department	1290 Athens Street, Gainesville, 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 9, 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:
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on proficiency test (PT) record review and staff interview, the laboratory failed to maintain a copy of all PT records as required. Findings include: 1. Medical Laboratory Evaluation (MLE) PT document review revealed the lack of an attestation statement for Habersham County for 2020 MLE-M3 -- KOH(potassium hydroxide) and Wet Prep(Wet Preparation). 2. An interview with Staff #3(CMS 209 form - Page 3) on March 9, 2021 at approximately 2:00 PM in the conference room confirmed the aforementioned lack of attestation statement.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)

	All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on proficiency test (PT) record review and staff interview, the laboratory failed to document corrective action for unsatisfactory scores. Findings include: 1. Medical Laboratory Evaluation(MLE) PT records revealed the laboratory scored 50% (fifty percent) and failed to document corrective action for 2020 MLE-M1 -- KOH (potassium hydroxide) and Wet Prep(Wet Preparation) in Stephens County. 2. An interview with Staff #3 (CMS 209 form- page 3) on March 9, 2021 at approximately 2: 20 PM in the conference room, confirmed the aforementioned lack of corrective action.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of the Standard operation manual (SOP), review of laboratory records, and staff interview, the laboratory failed to verify the accuracy of the quality assessment (QA) program. Findings include: 1. Review of the SOP revealed the lab has a policy/procedure (P&P) to assess, monitor and correct problems. 2. Review of the laboratory's records revealed no documentation for monitoring and evaluating of the aforementioned P&P . 3. Interview with Staff #3 (CMS 209 form - Page 3) on March 9, 2021 at 1:24 PM, confirmed the laboratory lacked documentation of following the aforementioned P&P.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) 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. This STANDARD is not met as evidenced by: Based on review of maintenance logs and staff interview, the lab failed to ensure professional maintenance on all microscopes per the procedure manual (SOP). Findings include: 1. Review of maintenance logs revealed 3 microscopes of Banks County with serial numbers 120927, 140587, and 123557 did not have professional maintenance documented for 2019. 2. Review of maintenance logs revealed the 3 microscopes of Hart County with serial numbers BX981276, 996805, and 1816425 did not have professional maintenance documented for 2019. 3. Interview with staff #3 (CMS 209 form - Page 3) on 03/09/21 in the conference room at approximately 1: 00 PM, confirmed the lack of the aforementioned professional maintenance.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR

	CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of the laboratory policy and procedure manual (SOP) and staff interview, the Laboratory Director (LD) failed to provide overall management and direction of the laboratory as required. Findings include: 1. For details refer to D6032.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory policy and procedure manual (SOP) and staff interview, the laboratory director (LD) failed to specify in writing the duties and responsibilities of each individual engaged in the performance of all phases of testing as required. Findings include: 1. SOP review revealed the lack of a Duties and Responsibilities policy and procedure. 2. An interview with Staff #3 (CMS 209 - Page 3) on March 9, 2021, in the conference room at approximately 1:00 p.m. confirmed the SOP did not contain the aforementioned policy and procedure. This is a Repeat Deficiency.