Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0883358	03/22/2018
Name of Provider or Supplier	**Street Address, City, State**	
Atlanta Health Associates, Inc	309 Pirkle Ferry Rd Ste D-300, 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 22, 2018. 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:
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory policy and procedure manual (SOP) and staff interview, the laboratory failed to make available a written procedure for all tests, assays, and examinations performed by the laboratory. Finding include: 1. Laboratory SOP review revealed the laboratory failed to make available a policy and procedure for sterility check of the inhouse-manufactured media. 2. An interview with Staff #2 (CMS 209) on 3/22/18 in a conference room at approximately 1:00 p.m. confirmed the laboratory failed to establish a policy and procedure for sterility check of the inhouse-manufactured media.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or

	produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory quality control (QC) documents and staff interview, the laboratory failed to perform media sterility checks as required. Findings include : 1. QC document review revealed the laboratory failed to perform sterility checks for their inhouse-manufactured media for 2016, and 2017, and 2018 thus far. 2. An interview with Staff #2 (CMS 209) on 3/22/18 in a conference room at approximately 1:00 PM confirmed sterility checks were not performed on inhouse-manufactured media for 2016, 2017, and 2018 thus far.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as 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 result reporting and whether supervisory 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 revealed the laboratory director (LD) failed to specify in writing the responsibilities and duties of the laboratory director (LD), clinical consultant(CC), technical supervisor (TS), general supervisor (GS), and testing personnel (TP) involved in all phases of the testing process. Findings include: 1. SOP review revealed the LD failed to specify in writing the duties and responsibilities of the following laboratory positions: LD, CC, TS, GS, and TP. 2. An interview with Staff #2 (CMS 209) on 3/22/18 in a conference room at approximately 1 p.m. confirmed the aforementioned duties and responsibilities were not included in the SOP.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on testing personnel (TP) competency document review and staff interview, the technical supervisor (TS) failed to evaluate and document the performance of TP responsible for high complexity testing at least semiannually during the first year the individual tested patient specimens. Findings include: 1. TP competency document review revealed the TS failed to perform a six-month competency for Staff #4 (CMS

	209) in 2016. 2. An interview with Staff #2 (CMS 209) in a conference room on 3/22 /18 at approximately 1:00 p.m. confirmed the TS did not perform a six-month competency for Staff #4 (CMS 209) in 2016.