Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D2137875	10/15/2018
Name of Provider or Supplier	**Street Address, City, State**	
Northeast Georgia Diagnostic Assoc And Clinic, Llc	1270 Friendship Road, #100, Braselton, 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 Clinical Laboratory Improvement Amendments (CLIA) survey was completed on October 15, 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:
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 the PT samples into the patient workload as required. Findings include: 1. American Association of Bioanalysts PT document review revealed the LD failed to provide attestation statements for 2018 --Event 1-- Non-Chemistry (Hematology) and Urinalysis. 2. An interview with the Technical Supervisor on 10/15/18 in a medical office at approximately 2:00 p.m. confirmed the aforementioned lack of attestation statements.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental

	conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (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 monitor over time the accuracy and precision of test performance as required. Findings include: 1. QC document review revealed microscopic urinalysis QC was not performed in 2017 and 2018 thus far. 2. An interview with the Technical Supervisor on 10/15/18 in a medical office at approximately 2:00 p.m. confirmed microscopic urinalysis QC was not performed for 2017 and 2018 thus far.
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 laboratory testing as required. Findings include: 1. TP competency document review revealed the TS failed to perform a six-month competency for Staff #3 (CMS 209) in 2018. 2. An interview with the TS on 10/15/18 in a medical office at approximately 2:00 p.m. confirmed the aforementioned competency was not performed in 2018.