Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D2137875	09/13/2022
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	A proficiency testing desk review was completed on September 13, 2022. At the time of the review, the laboratory was not in compliance with the Clinical Laboratory Improvement Amendments of 1988, 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on proficiency testing desk review using the Centers for Medicare and Medicaid (CMS) Casper Reports 155 and 153 and review of the laboratory's proficiency testing (PT) reports, the laboratory failed to maintain satisfactory performance in two consecutive events (1st and 2nd events of 2022), resulting in the

	first unsuccessful occurrence for General immunoology # 065 including: RA/RF # 225. Findings include: Refer to D 2075
D2075	GENERAL IMMUNOLOGY CFR(s): 493.837(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on proficiency testing desk review using the Centers for Medicare and Medicaid (CMS) Casper Reports 155 and 153 and review of the laboratory's proficiency testing (PT) reports, the laboratory failed to maintain satisfactory performance in two consecutive testing events (1st and 2nd events of 2022), resulting in the first unsuccessful performance for RA/RF, analyte # 225. Findings include: 1. Desk review of Casper Reports 153 and 155 disclosed the laboratory failed analyte # 225 RA/RF on event 1 of 2022 with a score of 60%, and event 2 with a score of 40%. 2. Desk review of the laboratory's proficiency testing reports from American Association of Bioanalysts (AAB) confirmed the laboratory failed RA/RF on Events 1 & 2 of 2022 resulting in the first unsuccessful performance.
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 proficiency testing desk review using the Centers for Medicare and Medicaid (CMS) Casper Reports 155 and 153 and review of the laboratory's proficiency testing (PT) reports, the laboratory director failed to ensure the laboratory maintained satisfactory performance in two consecutive events (1st & 2nd events of 2022), resulting in the first unsuccessful occurrence for Rheumatoid Factor (RF), analyte # 225. Findings include: Refer to D 6016
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on proficiency testing desk review using the Centers for Medicare and Medicaid (CMS) Casper Reports 155 and 153 and review of the laboratory's proficiency testing (PT) reports, the laboratory director failed to ensure the laboratory

	maintained satisfactory performance in two consecutive events (1st & 2nd event of 2022), resulting in the first unsuccessful occurrence for RA/RF, analyte # 225. Findings include: 1. Desk review of Casper Reports 153 and 155 disclosed the laboratory failed analyte # 225 , RF/RA on event 1 of 2022 with a score of 60%, and event 2 of 2022 with a score of 0%. 2. Desk review of the laboratory's proficiency testing reports from American Association of Bioanalysts (AAB) confirmed the laboratory failed RA/RF on events 1 & 2 of 2022, resulting in the first unsuccessful performance.