| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 11D0261374 | 09/13/2022 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Northeast Georgia Diagnostic Assoc And Clinic, Llc | 1240 Jesse Jewel Parkway, Suite 500, 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 |
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| **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 condition level deficiencies were cited: D2016 - 42 C.F.R. 493.803 Successful participation [proficiency testing] D6000 - 493.1403 Laboratory Director, Moderate Complexity |
| **D2016** | SUCCESSFUL PARTICIPATION<br>CFR(s): 493.803(a)(b)(c)<br><br>(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.<br><br>This CONDITION is not met as evidenced by:<br>Based on proficiency testing desk review using the Centers for Medicare and |

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| | 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 three consecutive events (3rd event of 2021, 1st and 2nd events of 2022), resulting in the second unsuccessful participation for General Immunology including: Rhematoid Arthritis/Rheumatoid Factor (RA/RF). |
| **D2084** | GENERAL IMMUNOLOGY<br>CFR(s): 493.837(f)<br><br>Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.<br><br>This STANDARD is not met as evidenced by:<br>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 American Association of Bioanalysts (AAB) proficiency testing (PT) reports, the laboratory failed to maintain satisfactory performance in three consecutive testing events (3rd event of 2021, 1st and 2nd events of 2022), resulting in the second unsuccessful performance for Rhematoid Arthritis/Rheumatoid Factor (RA/RF). Findings include: 1. A review of Casper Reports 153 and 155 disclosed the laboratory failed RA/RF on the following: 2021 Event 3 RF/RA Score 60% 2022 Event 1 RF/RA Score 60% 2022 Event 2 RF/RA Score 40% 2. A review of the laboratory's proficiency testing reports from American Association of Bioanalysts (AAB) confirmed the laboratory failed RA/RF for the following: 2021 Event 3 RF/RA Score 60% 2022 Event 1 RF/RA Score 60% 2022 Event 2 RF/RA Score 40% |
| **D6000** | MODERATE COMPLEXITY LABORATORY DIRECTOR<br>CFR(s): 493.1403<br><br>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.<br><br>This CONDITION is not met as evidenced by:<br>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 American Association of Bioanalysts (AAB) proficiency testing (PT) reports, the laboratory director failed to provide overall management and direction for ensuring immunology proficiency testing were tested as required under Subpart H. Refer to D6016. |
| **D6016** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(4)(i)<br><br>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; |

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| | This STANDARD is not met as evidenced by:<br>Based on proficiency testing review using the Centers for Medicare and Medicaid (CMS) Casper Reports 155 and 153 and review of the laboratory's American Association of Bioanalysts (AAB) proficiency testing (PT) reports, the laboratory director failed to ensure immunology proficiency testing was tested as required under Subpart H. The laboratory failed to maintain satisfactory performance in three consecutive testing events (3rd event of 2021, 1st and 2nd events of 2022), resulting in the second unsuccessful performance for RA/RF. Refer to D2084 |