Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0261736	03/27/2023
Name of Provider or Supplier	**Street Address, City, State**	
Northeast Georgia Physicians Group Toccoa	58 Big A Road, Toccoa, 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 March 27, 2023. 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 deficiencies were cited: D2016 - 42 CFR 493.803 Condition: Successful participation [proficiency testing] D6000 - 42 CFR 493.1403 Condition: Moderate Complex Laboratory Director
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 review of the CASPER 155 report and review of the American Proficiency Institute (API) reports, the laboratory failed to maintain satisfactory proficiency

	testing (PT) participation for Total Bilirubin (TBIL) in 2022 event 2 and 2023 event 1, resulting in an initial unsuccessful participation for TBIL. Refer to D 2096
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f) 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. This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid (CMS) CASPER 155 report and review of American Proficiency Institute (API) reports, the laboratory failed to maintain satisfactory participation in two of three testing events (2nd event of 2022 and 1st event of 2023), resulting in an initial unsuccessful participation for Total Bilirubin (TBIL). Findings: 1. A review of Casper Report 155 revealed the laboratory failed TBIL on the following: 2022 Event 2 TBIL Score 60% 2023 Event 1 TBIL Score 60% 2. A review of the laboratory's API Reports confirmed the laboratory failed TBIL with the aforementioned scores.
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 Centers for Medicare and Medicaid (CMS) CASPER 155 report and review of the American Proficiency Institute (API) reports, the laboratory director failed to ensure the laboratory maintained satisfactory performance in two of three testing events (2nd event of 2022 and 1st event of 2023), resulting in the initial unsuccessful participation in Total Bilirubin (TBIL). 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 review of the Centers for Medicare and Medicaid (CMS) CASPER 155 report and review of the American Proficiency Institute (API) reports, the laboratory director failed to ensure the laboratory maintained satisfactory performance in two of three testing events (2nd event of 2022 and 1st event of 2023), resulting in the initial unsuccessful participation in Total Bilirubin (TBIL). Refer to D 2096