

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0892703	(X3) Date Survey Completed 05/11/2021
Name of Provider or Supplier Northeast Georgia Physicians Group Cumming	Street Address, City, State 2825 Keith Bridge Road Suite 100, 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 May 11, 2021. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency test (PT) records, CMS 209 form, and staff interview, the laboratory failed to rotate PT sample testing among all laboratory testing personnel (TP). Findings include: 1. Review of the CMS 209 personnel form reveals 2 TP are employed by the lab. 2. Review of the American Proficiency Institute (API) PT records reveals Staff #3 (CMS 209 form) performed all PT samples in the API 2019 Event #3; 2020 Events # 1, 2, & 3; and 2021 Event #1. 3. Interview at approximately 12:05 PM with staff #3 (CMS 209 form) on 05/11/21 in the breakroom, confirms she performed all aforementioned PT.</p>
D5805	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units</p>

of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on lab report review and staff interview, the laboratory failed to include all the required information on the laboratory test reports. Findings include: 1. Review of patient report #000091730 reveals the lack of the name and address of the laboratory location where the test was performed (Northeast Georgia Medical Center/ GSV). 2. An interview with Staff #3 (CMS 209) in the breakroom on 05/11/2021 at approximately 11:30 a.m. confirmed the lack of the laboratory location where the test was performed.