

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0997747	(X3) Date Survey Completed 05/17/2022
Name of Provider or Supplier Northeast Georgia Physicians Group	Street Address, City, State 4754 Martin Road, Flowery Branch, 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 17, 2022. 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:
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on American Proficiency Institute (API) testing records review and interview with the laboratory coordinator, the laboratory failed to have successful performance in two out of three consecutive testing events. Findings include: 1.) American Proficiency Institute (API) documents review revealed the laboratory failed to have successful performance in 2020 (0%) Event#1 and 2020 (0%) Event #2 for Vaginal Wet Preparation (KOH), resulting in an "Unsuccessful Participation" in a non-regulated analyte. 2.) An interview with the laboratory coordinator on 05/17/2022 at approximately 12:35 PM in the review room confirmed the above findings in 2020.</p>
D6018	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii)</p> <p>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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to</p>

identify any problems that require corrective action;

This STANDARD is not met as evidenced by:

Based on API (American Proficiency Institute) Proficiency Testing(PT) documents review and staff interview, the laboratory director (LD) failed to ensure that Proficiency Testing(PT) was done on a timely manner and results submitted to the appropriate agency in 2020. Findings include: 1. PT document review revealed that the LD failed to ensure Provider Performed Microscopy (PPM) (Vaginal Wet Preparation KOH) PT was done in the 1st Event of 2020. The absence of the 1st Event in 2020 and 0% in the 2nd Event of 2020 resulted in an "Unsuccessful" performance grade by API. 2. An interview with the laboratory coordinator on 05/17/2022, at approximately 12:24 pm in the review room confirmed no participation in Event #1 and 0% in Event #2 of 2020.