

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D1100377	(X3) Date Survey Completed 01/13/2020
Name of Provider or Supplier Northeast Georgia Physicians Group	Street Address, City, State 1315 Jesse Jewell Parkway, Suite 200 & 201, 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
D0000	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on January 13, 2020. 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:
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on staff interviews during the laboratory tour and procedure manual review, it was determined that the laboratory was not following its own wet prep guidelines for PPM(Provider Performed Microscopy) testing of OB-GYN patient samples in 2018 and 2019. Findings include: 1.) Staff interviews during laboratory tour revealed testing personnel (TP) (#s 7 - 19, CMS 209) performed wet preps on OB-GYN patients without using KOH prep solution. The attached procedure manual clearly states use 10% KOH solution for Fungal elements detection. 2.) An interview with the laboratory coordinator and (TP #2, CMS 209) at approximately 11:45 am on 01/13 /2020 in the conference room confirmed the OB-GYN practitioners were not following their procedure for wet preps in 2018 and 2019.</p>
D6054	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the</p>

performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:

Based on Personnel competency records review and an interview with the laboratory coordinator, the (TC) who is also the laboratory director failed to perform annual competencies on medical practitioners performing PPM Microscopy in 2018 and 2019. Findings include: 1. Annual competencies were not performed on medical practitioners (TPs #7 - 19 CMS 209) performing PPM microscopy in 2018 and 2019. 2. An interview with the laboratory coordinator and (TP #2 CMS 209) on 01/13/2020 in the conference room at approximately 11:55 a.m. confirmed annual competencies were not performed on medical practitioners by the Technical Consultant(TC), who is also the laboratory director in 2018 and 2019.