

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D2124751	(X3) Date Survey Completed 02/16/2021
Name of Provider or Supplier Pcg Molecular Llc	Street Address, City, State 755 Mount Vernon Hwy, Ne, Ste 230, Atlanta, 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
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on lack of enrollment documentation and an interview with the lab director, the laboratory failed to enroll in proficiency testing (PT) program for testing the SARS-CoV-2 assay. Findings include: 1. Due to the lack of enrollment documentation, when requested, the lab was unable to verify the enrollment in a PT program. 2. Interview with the lab director in his office on 2/10/21 at approximately 3:00 PM, confirmed the lab had not enrolled in a PT program at the time of the survey.</p>