

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0300834	(X3) Date Survey Completed 03/31/2021
Name of Provider or Supplier Art Fertility Program Of Alabama	Street Address, City, State 2006 Brookwood Medical Center Drive, Suite 508, Birmingham, AL	
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
D2006	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)</p> <p>The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the American Association of Bioanalysts (ABB) Proficiency Testing records, procedure manual, and an interview with Testing Personnel #1, the laboratory failed to test the proficiency testing samples in the same manner as it tests patient specimens. This was noted on ten out of fourteen 2018 - 2020 Chemistry and Nonchemistry Proficiency Testing Events. The findings include: 1. A review of Proficiency Testing records revealed proficiency samples were performed twice before results were submitted to American Association of Bioanalysts. The following events had samples repeated: a) Chemistry 3rd Event 2018 b) Chemistry 1st Event 2019 c) Chemistry 3rd Event 2019 d) Chemistry 2nd Event 2020 e) Nonchemistry 3rd Event 2018 f) Nonchemistry 1st Event 2019 g) Nonchemistry 2nd Event 2019 h) Nonchemistry 3rd Event 2019 i) Nonchemistry 2nd Event 2020 j) Nonchemistry 3rd Event 2020 2. A review of the Procedure Manual: Proficiency Testing Program stated "4. Testing...b. Specimens are processed in a timely manner and are treated in the same manner as patient material." However, the Procedure Manual did not include a</p>

protocol of repeating testing for all patient samples. 3. During an interview on 03/31/2021 at 10:30 AM, Testing Personnel #1 confirmed most repeats were performed to confirm proficiency testing results and patient testing is not performed in this manner.