

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0981283	(X3) Date Survey Completed 03/27/2024
Name of Provider or Supplier Anwan Wellness Medical Center	Street Address, City, State 725 North Central Avenue, Hapeville, 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	An onsite survey was completed on March 27, 2024, to investigate complaint number GA00237528. The allegation was substantiated. The following deficiencies were cited:
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on observation during the laboratory tour and staff interview, the laboratory failed to follow current manufacturer's instructions for all waived tests performed by the Clinic's laboratory as required in 2023 and 2024. Findings: 1. Observation during the laboratory tour on 03/27/2024 at approximately 10:40 a.m. revealed there were no manufacturer's instructions available at the time of survey for the following waived tests: Urinalysis(Clinitek Status), DCA Vantage Analyzer for HgBA1C, One Step +Strep Tests, Abbott Lipid profile, Hemacue Hgb and Glucose screen and Accutest ValuPAK HCG Pregnancy tests. 2. Observations during the tour and laboratory documents maintenance review on 03/27/2027 at approximately 11:00 a.m. revealed there were no required Quality Control (QC) documentations available at the time of survey for the aforementioned waived tests from 2023 to day of survey 03/27/2024. 3. Interviews with staff and Clinic administrator on the phone at approximately 11:30 a. m. on 03/27/2024 confirmed the lack of manufacturer's instructions and Quality Control (QC) documentations for the aforementioned waived tests from 2023 to day of survey 03/27/2024.</p>