

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0699024	(X3) Date Survey Completed 01/31/2023
Name of Provider or Supplier Medical Center, Llp, The	Street Address, City, State 908 Hillcrest Pkwy, Dublin, 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 recertification survey was performed on January 31, 2023. The facility was found to be NOT in compliance with all applicable CLIA requirements for specialties /subspecialties for 42 CFR.
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 lab tour, review of manufacturer insert, and staff interview, the laboratory was not following the manufacturer instructions for the placement of the tube rack, used to perform the Globe Scientific, INC., Sedi-Rate E.S. R. system (ESR), Erythrocyte Sedimentation Rate waived test. Findings: 1. During the tour of the laboratory, it was observed that the rack used to hold the Westergren E.S. R. tubes, in the performance of testing was sitting on the counter beside a centrifuge. There was a patient sample in the rack as the centrifuge was spinning, causing the patient sample to vibrate. 2. Review of the package insert for the ESR test, the manufacturer states: "PRECAUTION: The rack and test unit must remain vertical in an area free from vibrations, drafts, and direct sunlight. NOTE: To ensure a completely level testing surface, use out acrylic leveling platform in conjunction with the appropriate rack." 3. Interview with the Technical Consultant and the laboratory supervisor, on 01/31/2023, at approximately 10:30 am in the laboratory, confirmed the aforementioned statements. It was also confirmed that the 956 samples that were resulted over the last 12 months for the ESR testing, were not validated as accurate, there was no Quality Control performed each day of patient testing.</p>