

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2266273	(X3) Date Survey Completed 04/27/2023
Name of Provider or Supplier Mobile Men's Health-Mobile	Street Address, City, State 1110 Montlimar Drive Suite 560, Mobile, 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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the Procedure Manual and an interview with the Director of Clinic Operations, the laboratory failed to establish a written procedure for Qualigen Fast Pack IP System Testosterone. This was noted from the date of implementation of the Procedure Manual, 9/1/2022, to the date of the current survey, 4/27/2023. The findings include: 1. A review of the Procedure Manual revealed a lack of a written procedure for Testosterone on the Qualigen Fast Pack IP System. 2. During an interview on 4/27/2023 at 11:00 AM, the Director of Clinic Operations stated, "The company never sent us a procedure, only the QA manual for the instrument".</p>