Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2173624	(X3) Date Survey Completed 03/18/2024
Name of Provider or Supplier Lpg Urology - Fort Myers	**Street Address, City, State** 12651 Whitehall Drive, Fort Myers, FL	

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 announced CLIA recertification survey was conducted at LPG Urology - Fort Myers on 03/18/2024. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiency:
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) 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. This STANDARD is not met as evidenced by: Based on observation, record review, and staff interview with the Technical Consultant, the laboratory failed to follow the Centrifuge Maintenance and Urine Microscopic Examination procedures for calibration and timing for two out of two years (2022-2024) reviewed. The annual test volume for urinalysis was 8654. Findings included: Observation on 03/18/2024 at 10:10 AM, showed the laboratory had two Horizon 642E Centrifuges (Centrifuge 1 and 2). Centrifuge 1 (serial number 191213FA140) had a "Factory Calibration" of 3312 revolutions per minute (RPM), and Centrifuge 2 (serial number 191213EZ630) had a "Factory Calibration" of 3308 RPM. On 03/18/2024 at 10:30 AM, the Technical Consultant stated both Centrifuges were used for urine microscopic examinations. Record review of the "Centrifuge Maintenance" policy and procedure, signed and dated by the Laboratory Director on 11/25/2019, showed "POLICY: 2. The timers and speed will be checked for accuracy annually. PROCEDURE: 2. Check Operating Speed a. The operating speed, the acceptable range for the operating speed, and the speed control setting for the operating speed is logged on the Centrifuge RPM and Timer Record. 3. Check Timer a. Timer checks will be performed on centrifuges if timing is critical for those tests

	/specimens being processed in that centrifuge." Record review of the "Centrifuge Maintenance" records 2022 through 2024 revealed the columns for RPM's and Timer were blank. Record review of the "Urine Microscopic Examination" procedure, dated November 2023 and signed by the Laboratory Director, showed "After chemical analysis, centrifuge urine specimen in the conical tube for 5 minutes at 1500 rpm." On 03/18/24 at 10:50 AM, the Technical Consultant confirmed the laboratory had not been recording the Centrifuges timers and speed annually and was not aware of the discrepancy in RPM of the factory calibrations and the laboratory's "Urine Microscopic Examination" procedure.