Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2280404	(X3) Date Survey Completed 09/18/2023
Name of Provider or Supplier Tmmc, Pc	**Street Address, City, State** 2001 Mallory Lane Ste 302, Franklin, TN	

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
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the manufacturer control package inserts, and staff interview, the laboratory failed to label control vials used for performing testosterone quality control (QC) on the Qualigen FastPack IP analyzer with corrected expiration date. The findings include: 1. Observation of the laboratory on 9/18/23 at 8:30 am revealed the following: - Qualigen FastPack IP (SN: 1159) chemistry instrument in use for testosterone testing. - Two levels of opened FastPack controls (Lot: 2305031-1) in use for testosterone QC and were not labeled with an open date or corrected expiration date. 2. Review of the manufacturer control package inserts revealed the opened vials of FastPack controls are stable for 120 days when stored at 2 - 8 degrees Celsius (C). 3. Interview with the regional manager on 9/18/23 at 11:00 am confirmed the laboratory failed to label controls used to monitor testosterone patient testing with corrected expiration date for two of two control vials observed on the date of the survey (9/18/23).