Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2183854	11/25/2024
Name of Provider or Supplier	**Street Address, City, State**	
Tmmc, Pc	210 23rd Ave N #201, Nashville, 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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the laboratory's quality control (QC) records, lack of records, and staff interview, the laboratory failed to retain three of three manufacturer package inserts for quality controls used for the Qualigen FastPack IP analyzer used for patient testing in 2023 and 2024. The findings include: 1. Observation of the laboratory on 11/25/2024 at 09:00 a.m. revealed a Qualigen FastPack IP analyzer (serial number 1115) in use for patient testing for testosterone. 2. A review of the laboratory's QC records revealed the following Qualigen Control Kit Lot numbers in use: - Lot 2210005 on 6/30/2023. - Lot 2305031 on 11/8/2023 and 5/2/2024. - Lot 2310029 on 9/17/2024. 3. The laboratory was unable to provide the manufacturer QC package inserts for Qualigen Control Kit lots 2210005, 2305031, and 2310029 on the date of survey. 4. An interview with the senior director of compliance and operations on 11/25/2024 at 12:00 p.m. confirmed the survey findings.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

	This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services form CMS-209, personnel records, and staff interview, the laboratory failed to assess and document annual employee competency testing for one of three testing personnel in 2024. The findings include: 1. A review of the form CMS-209 revealed three testing personnel listed for moderately complex testing. 2. A review of the laboratory's personnel records revealed no documented annual competency assessment in 2024 for testing personnel one of three listed on the CMS-209. 3. An interview with the senior director of compliance and operations on 11/25/2024 at 12:00 p.m. confirmed the survey findings.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the laboratory's calibration records, and staff interview, the laboratory failed the perform calibration verification for testosterone at six-month intervals from November 2023 to November 2024 (three testing periods). This deficiency was cited at the previous survey (4/11/2023) and the laboratory failed to maintain compliance. The findings include: 1. Observation of the laboratory on 11/25/2024 at 09:00 a.m. revealed a Qualigen FastPack IP analyzer (serial number 1115) in use for patient testing for testosterone. 2. Review of the laboratory's calibration records revealed no calibration verification documentation from November 2023 to November 2024. 3. An interview with the senior director of compliance and operations on 11/25/2024 at 12:00 p.m. confirmed the survey findings.