

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  44D2183854	<b>(X3) Date Survey Completed</b>  04/11/2023
<b>Name of Provider or Supplier</b>  Tmmc, Pc	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5401</b>	<p><b>PROCEDURE MANUAL</b> 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 review of the procedure manual and interview with the regional director, it was determined that the laboratory failed to follow the Manual Review procedure. The findings include: 1. Review of the laboratory's procedure manual revealed a policy entitled "Manual Review", which states "Laboratory Personnel must document review of this manual by signing below" 2. Review of the procedure manual's signature page revealed two of two testing personnel did not sign the signature page indicated by the laboratory's Manual Review procedure. 3. Interview with the regional director on April 11, 2023 at 1:00 pm confirmed the lab staff did not document review of the laboratory's procedure manual.</p>
<b>D5439</b>	<p><b>CALIBRATION AND CALIBRATION VERIFICATION</b> CFR(s): 493.1255(b)</p> <p>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</p>

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 review of the laboratory's calibration records and interview with the regional director, the laboratory failed to ensure that calibration verification for testosterone was performed at six month intervals from 2021 to 2023. The findings include: 1. A review of calibration records for the chemistry analyzer performing testosterone testing revealed the following: -Calibration of testosterone is not performed using at least three levels of calibrators that span the reportable range. -No calibration verification documentation for the period of April of 2021 to April of 2023. 2. An interview with the regional director at 1:00 pm on April 11, 2023 confirmed the calibration verifications for the chemistry analyzer were not performed at six month intervals from 2021 to 2023.

**D5481**

**CONTROL PROCEDURES**

CFR(s): 493.1256(f)(g)

(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of final patient reports, quality control (QC) logs, and interview with the regional director, the laboratory failed to obtain acceptable quality control results prior to reporting patient results on 04/29/2021. The findings include: 1. Review of randomly selected patient reports revealed testosterone testing for one patient (ID: 679) was reported on 04/29/2021. 2. Review of daily testosterone control logs for April 2021 revealed no QC results recorded for 04/29/2021. 3. Interview with the regional director on April 11, 2023 at 1:00 pm confirmed that acceptable QC for testosterone was not obtained prior to reporting patient results on 04/29/2021.

**D5805**

**TEST REPORT**

CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for

acceptability.

This STANDARD is not met as evidenced by:

Based on review of final patient test reports and interview with the regional director, the final patient test reports did not include the laboratory name or specimen source for testosterone. The findings include: 1) Review of the final report for patient numbers one (679), two (1305), three (1576), and four (10410) in the electronic medical record revealed the testing laboratory name was not listed. 2) Interview with the regional director on April 11, 2023 at 1:00 p.m. confirmed the laboratory's final patient test reports did not include the testing laboratory name.

**D6004**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(a)(b)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

Based on review of the "Laboratory Personnel Requirements and Responsibilities" policy, personnel records, and staff interview, the laboratory director failed to perform competency assessment for the technical consultant in 2021 and 2022. The findings include: 1. The laboratory's "Laboratory Personnel Requirements and Responsibilities" policy states the following: - Laboratory personnel records will be maintained for each person in the position of Laboratory Director, Clinical Consultant, Technical Consultant, Testing Personnel, and additional support staff. - Laboratory personnel records will include Competency Assessment records. 2. Review of the laboratory personnel records revealed the following: - Delegation of technical consultant (TC) duties to one TC. - No records for documentation of technical consultant competency by the director of the lab were available for 2021 and 2022. 3. Interview with the regional director on April 11, 2023 at 1:00 pm confirmed the laboratory director failed to ensure competency assessments were performed for the technical consultant in 2021 and 2022.