Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2106191	02/25/2022
Name of Provider or Supplier	**Street Address, City, State**	
Modern Male T Clinic	1801 Durham # 4, Houston, TX	

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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
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 a review of the FastPack IP System Quality Assurance Log, the laboratory's calibration verification records for the Qualigen FastPack IP systems from 2021, and staff interview, it was revealed that the laboratory failed to have documentation of performing one of two calibration verification procedures in 2021 for testosterone testing on the two Qualigen FastPack IP system analyzers. Findings include: 1. A review of the FastPack IP System Quality Assurance Log (65000160 Rev. 006 06/15) revealed the following: "Calibration Verification- Complete the system method verification every 6 months using the Testo Method Verification Kit." 2. A review of the calibration verification records from 2021 revealed the following dates when a calibration verification was performed for Total Testosterone: Analyzer 0789: - 2/6/21 Analyzer 0466: - 2/6/21 *There was no documentation of a second calibration verification on the 2 Qualigen FastPak IP systems in 2021 for testosterone testing. 3. An interview with the medical director on 2/25/22 at 11:20 a.m. in the break room, after review of the records, confirmed the above findings.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of the laboratory's IQCP (Individualized Quality Control Plan) for the two Qualigen FastPack IP system analyzers, the laboratory's quality control records from 2021, a review of the laboratory's patient test records, and staff interview, it was revealed that the laboratory failed to have documentation of running the quality controls on the two Qualigen FastPack IP system analyzers at the frequency established by the IQCP for four of 49 days from February 2021 to December 2021. Findings include: 1. A review of the laboratory's IQCP for the two Qualigen FastPack IP system analyzers (serial numbers: 0466 and 0789) used for testosterone testing revealed the laboratory tested the FastPack Control Kit (levels 1 and 2) every 7 days or with new shipment/lot of testing materials. 2. A review of the laboratory's quality control (QC) records from February 2021 to December 2021 revealed the laboratory ran the quality controls beyond the frequency of 7 days, as indicated in the laboratory's IQCP, on the following 4 days: Qualigen FastPack IP analyzer 0466 QC performed: 2/10/21 Next time QC performed: 2/19/21 Time elapsed between QC runs: 9 days Qualigen FastPack IP analyzer 0466 QC performed: 10/20/21 Next time QC performed: 10/29/20 Time elapsed between QC runs: 9 days Qualigen FastPack IP analyzer 0466 QC performed: 11/17/21 Next time QC

	performed: 12/1/21 Time elapsed between QC runs: 14 days Qualigen FastPack IP analyzer 0466 QC performed: 12/6/21 Next time QC performed: 12/15/21 Time elapsed between QC runs: 9 days 3. A review of the laboratory's patient test records revealed the laboratory ran the following 3 patient's testosterone tests when the QC was run beyond the frequency indicated in the IQCP: Patient: 05011981 Patient: 08311973 Patient: 12161961 4. An interview with the medical director on 2/25/22 at 10:20 a.m. in the break room, after review of the records, confirmed the above findings.
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 a review of the laboratory's policies, a review of the laboratory's quality control records from August 2020 to July 2021, a review of the laboratory's patient test records, and staff interview, it was revealed that the laboratory failed to ensure quality control values were acceptable prior to reporting patient test results for two of 47 days reviewed for testosterone testing on the two Qualigen FastPack IP system analyzers. Findings include: 1. A review of the laboratory's policy titled 'Quality Assurance' revealed the following: "For each QC event, ensure two levels of quality control are tested and are within acceptable ranges before patients are tested." 2. A random review of quality control records from August 2020 to July 2021 revealed the following 2 of 47 days when 2 levels of quality control (QC) were outside of the acceptable ranges for testosterone testing: 8/25/20 Qualigen FastPack IP analyzer SN: 0466 Testosterone QC result: 133 (acceptable range 140-340) No corrective action documented 7/28/21 Qualigen FastPack IP analyzer SN: 0789 Testosterone QC result: 133 (acceptable range 140-340) Corrective action documented: "Control 1 failed, second attempt was not re-ran. Controls will be run next week" 3. A review of the laboratory's patient test records revealed the following 8 patients were run when 2 levels of QC were outside of the acceptable range: 8/25/20: Patient: 04271974 Patient: 08221975 7/28/21: Patient: 07131966 Patient: 09011976 Patient: 12141964 Patient: 11211977 Patient: 07071972 Patient: 01131959 4. An interview with the medical director on 2/25/22 at 10:45 a.m. in the break room, after review of the records, confirmed the above findings.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on a review of the laboratory's records and staff interview, it was revealed that the laboratory failed to ensure that four of four comparison studies were performed as

	required in 2020 and 2021 on the two Qualigen FastPack IP systems used for total testosterone testing. Findings included: 1. A review of the laboratory's records revealed the laboratory used 2 Qualigen FastPack IP systems (Serial Numbers: 0466 and 0789) for Total Testosterone testing in 2020 and 2021. 2. Further review of the laboratory's records revealed no documentation of, twice a year, evaluating the relationship between the testosterone analyte run on the two Qualigen FastPack IP systems by performing comparison studies in 2020 and 2021. 3. An interview with the medical director on 2/25/22 at 11:10 p.m. in the break room, after review of the records, confirmed the above findings.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of the laboratory's Daily Environmental Log Sheets for 2020, a random review of patient test records, and staff interview, it was revealed that the laboratory failed to have documentation of performing corrective action when the laboratory's room temperature was documented outside the acceptable range for 65 of 223 days from March 2020 to November 2020. Findings include: 1. A review of the laboratory's Daily Environmental Log Sheets for March 2020 to November 2020 revealed the following 65 days where the documented room temperature was outside the laboratory's acceptable range of 15 - 25C: 3/6/20 25.1 6/23/20 25.5 10/15/20 25.3 3/12/20 25.3 6/24/20 25.5 10/17/20 25.1 3/13/20 25.1 6/25/20 25.9 10/19/20 25.3 3/19/20 25.2 8/6/20 25.4 10/20/20 25.1 3/20/20 25.1 8/10/20 25.1 10/21/20 25.3 3/27/20 25.6 8/11/20 25.5 11/5/20 26.3 3/28/20 25.1 8/12/20 25.7 11/6/20 26.1 3/30/20 25.3 8/13/20 25.5 11/7/20 26.3 5/4/20 25.5 8/17/20 25.5 11/10/20 25.3 5/13/20 25.1 8/18/20 25.3 11/11/20 25.5 5/15/20 25.3 8/20/20 25.3 11/12/20 26.3 5/18/20 25.3 9/3/20 25.5 11/13/20 25.7 5/21/20 25.3 9/4/20 25.9 11/14/20 25.7 5/22/20 25.5 9/5/20 26.3 5/27/20 25.3 9/8/20 25.3 6/3/20 25.3 9/9/20 25.1 6/4/20 25.3 9/16/20 25.3 6/5/20 25.3 9/18/20 25.7 6/7/20 25.5 9/19/20 26.3 6/8/20 25.3 9/21/20 26.1 6/10/20 25.7 9/23/20 25.5 6/11/20 25.7 10/1/20 25.3 6/12/20 25.3 10/7/20 25.3 6/17/20 25.3 10/8/20 25.4 6/20/20 25.3 10/9/20 25.2 6/22/20 25.3 10/10/20 25.4 2. Further review of the Daily Environmental Log Sheets revealed a column titled 'Corrective Action'. For all of the above listed dates, there was no documentation, in the corresponding column, of the laboratory performing corrective action. 3. A random review of patient records revealed the following 16 patient's specimens were resulted when the laboratory's room temperature was documented outside of the acceptable range: Patient: 09281975 Resulted: 5/22/20 Patient: 11141968 Resulted: 5/22/20 Patient: 02151956 Resulted: 6/11/20 Patient: 10241968 Resulted: 8/12/20 Patient: 08051974 Resulted: 8/17/20 Patient: 09051982 Resulted: 8/17/20 Patient: 08021978 Resulted: 9/5/20 Patient: 01011988 Resulted: 9/21/20 Patient: 07101970 Resulted: 9/21/20 Patient: 08011981 Resulted: 9/21/20 Patient: 02151968 Resulted: 10/15/20 Patient: 04111975 Resulted:

	10/15/20 Patient: 11061975 Resulted: 10/15/20 Patient: 01241978 Resulted: 10/15/20 Patient: 12061977 Resulted: 11/7/20 Patient: 02141972 Resulted: 11/7/20 4. An interview with the medical director on 2/25/22 at 10:50 a.m. in the break room, after review of the records, confirmed the above findings. Key: C = degrees Celsius
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on a review of the laboratory's submitted CMS 209 form, the laboratory's personnel files, and staff interview, it was revealed that the laboratory failed to have documentation of the technical consultant evaluating the competency of two of two testing personnel for moderate complexity testing. Findings include: 1. A review of the laboratory's submitted CMS 209 form (signed by the laboratory director on 2/25 /22) revealed the laboratory identified 2 testing personnel performing moderate complexity testing. 2. A review of the laboratory's personnel records revealed that there was no documentation of the technical consultant evaluating the competency of the following testing personnel: - Testing person #1 - Testing person #2 * There were competency assessment forms for testing person #1 (competency form dated 1/3/22) and testing person #2 (competency form had no date), however, the technical consultant did not sign or initial as the reviewer and did not attest to competency being satisfactorily demonstrated. 3. An interview with the medical director on 2/25 /22 at 10:30 a.m. in the break room, after review of the records, confirmed the above findings.