

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D2106191	<b>(X3) Date Survey Completed</b>  12/02/2025
<b>Name of Provider or Supplier</b>  Modern Male T Clinic	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	The Modern Male T Clinic laboratory was found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780, CLIA requirements for laboratories as a result of a recertification survey on December 2, 2025 and (re)certification is recommended. Standard level deficiencies were cited.
<b>D2006</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)</p> <p>(b)The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing.</p> <p>This STANDARD is not met as evidenced by: Based on a review of American Proficiency Institute (API) attestation statements, the laboratory's policies, the laboratory's API proficiency testing records, and staff interview, the laboratory failed to test proficiency samples for Testosterone in the same manner it tested patient samples for four of six Chemistry Core events in 2024 and 2025. Findings include: 1. A review of the API attestation statement, signed by the laboratory's testing personnel for each proficiency testing event, revealed the following: "The undersigned certify that, as closely as possible, these proficiency testing samples were tested in the same manner as patient specimens." 2. A review of the laboratory's policy titled 'Proficiency Testing Policies' stated the following: "Follow your normal routine: Test PT samples in the same manner as you would patient samples. In other words, test PT samples with the regular patient workload using a staff member who routinely performs FastPack IP System testing. Do not</p>

repeat PT sample testing unless you would repeat a patient test in the same situation." 3. A review of the laboratory's API proficiency testing records for 2024 and 2025 revealed the proficiency test samples for Testosterone were tested on one FastPack IP System and then repeated (on the same day) on the other FastPack IP System for the following 4 testing events: a) 2024 Chemistry Core 1st Event - Samples IA-01 and IA-02 were run on 3/19/24 on analyzer serial numbers: 0789 and 1225 b) 2024 Chemistry Core 2nd Event - Samples IA-06 and IA-07 were run on 5/23/24 on analyzer serial numbers: 0789 and 1225 c) 2025 Chemistry Core 1st Event - Samples IA-01, IA-02, IA-03, IA-04, IA-05 were run on 1/27/25 on analyzer serial numbers: 0789 and 1225 d) 2025 Chemistry Core 3rd Event - Samples IA-11, IA-12, IA-13, IA-14, IA-15 were run on 8/20/25 on analyzer serial numbers: 1220 and 1225 4. In an interview on 12/2/25 at 10:45 a.m. in the break room, after review of the records, the technical consultant (as indicated on the CMS 209 form) confirmed that patient samples are only run on one FastPack IP System analyzer and not repeated on the second analyzer.

**D5221**

**EVALUATION OF PROFICIENCY TESTING PERFORMANCE**  
CFR(s): 493.1236(d)

All proficiency testing evaluation and verification activities must be documented.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's policies and forms, the laboratory's American Proficiency Institute (API) proficiency testing results, the laboratory's records, and staff interview, the laboratory failed to follow its policy for performing corrective actions for one of one proficiency testing event with unsatisfactory scores for Testosterone in 2024. Findings include: 1. A review of the laboratory's policy titled 'Quality Assurance Assessment Program for FastPack IP System Testing' revealed the following: "A corrective action plan is developed and implemented and an effective resolution is verified before resuming patient testing. These actions are recorded on the QA Assessment." 2. A review of the laboratory's Quality Assurance Assessment form revealed the following: "If PT failure occurred, attach a copy of the PT Checklist to this QA Assessment." 3. A review of the laboratory's API proficiency testing results from 2024 Chemistry- Core- 1st Event revealed the following unsatisfactory scores: Testosterone 50% 4. A review of the laboratory's records revealed no documentation of the laboratory completing a PT Checklist for the unsatisfactory scores received for the 2024 Chemistry- Core- 1st Event. 5. In an interview on 12/2/25 at 11:00 a.m. in the break room, after review of the records, the technical consultant (as indicated on the CMS 209 form) confirmed the above findings.

**D5291**

**GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT**  
CFR(s): 493.1239(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's policies, the laboratory's Quality Assurance Assessments, and staff interview, the laboratory failed to follow its policy by completing five of twelve monthly Quality Assurance Assessments in 2024. Findings

include: 1. A review of the laboratory's policy titled 'Quality Assurance Assessment' revealed the following: "Complete this assessment on a monthly basis." 2. A review of the laboratory's Quality Assurance Assessments from 2024 revealed the laboratory failed to have documentation of completing the assessments for the following 5 months: - January - February - March - April - May 3. In an interview on 12/2/25 at 10:45 a.m. in the break room, after review of the records, the technical consultant (as indicated on the CMS 209) confirmed the above findings.

**D5293**

**GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT**  
CFR(s): 493.1239(b)(c)

(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.

This STANDARD is not met as evidenced by:  
Based on a review of the laboratory's American Proficiency Institute (API) proficiency testing records, the laboratory's records, and staff interview, the laboratory failed to review the effectiveness of corrective action taken for one of one unsatisfactory score for the analyte Testosterone in 2024. Findings include: 1. A review of the laboratory's API proficiency testing records revealed the laboratory received a score of 50% for the analyte Testosterone for the 2024 Chemistry- Core-1st Event. The laboratory resulted the following: - Sample IA-01 1.2 Expected Result: 4.6 - 8.1 - Sample IA-02 9.0 Expected Result: 6.9 - 11.8 2. A review of the laboratory's records revealed the laboratory performed the following corrective action: "Controls and calibrations completed and passes. API sample was re-run. Results within given by API." 3. Further review of the laboratory's records revealed the laboratory failed to review the effectiveness of the corrective action taken for the unsatisfactory testosterone test. The following result was obtained when the API sample was re-run and the value was still not in the Expected Result range: - Sample IA-01 8.6 Expected Result: 4.6 - 8.1 4. In an interview on 12/2/25 at 11:20 a.m. in the break room, after review of the records, the technical consultant (as indicated on the CMS 209 form) confirmed the above findings.