

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2138091	(X3) Date Survey Completed 09/14/2026
Name of Provider or Supplier Modern Male T Clinic	Street Address, City, State 14550 Sh 121, #130, Frisco, 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	A recertification survey was completed on 09/14/2026. Standard level deficiencies were cited.
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) testing forms in 2026, CMS (Centers for Medicare & Medicaid Services) 209 form, and confirmed in staff interview, the laboratory failed to ensure patient samples were analyzed with the laboratory's regular patient workload by personnel who routinely perform testing in the laboratory for 6 of 6 events in 2025 (Events 1,2,3) and 2026 (Events 1,2,3). Findings Included: 1. Review of American Proficiency Institute (API) testing events, revealed Testing Person (TP-1) performed the following events: a. 2025 Chemistry 1st, 2nd and 3rd events b. 2026 Chemistry 1st, 2nd and 3rd events 2. Review of the laboratory's CMS 209 form submitted at the time of survey, revealed three Testing Persons (TP-1, TP-2, TP-3) were listed as performing moderate complexity testing (chemistry). TP-2 and TP-3 performed testing of patient specimens and did NOT participate in PT events. 3. In an interview with testing person 1 (TP-1) on 09/14/2026 at 10:25 AM in the facility, TP-1 confirmed the laboratory failed to ensure patient samples were analyzed with the laboratory's regular patient workload by personnel who routinely perform testing in the laboratory for 6 of 6 events in 2025 (Events 1,2,3) and 2026 (Events 1,2,3).
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)

(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.

This STANDARD is not met as evidenced by:

Based on review of laboratory policy, American Proficiency Institute (API) Proficiency Testing (PT) records in 2026, and confirmed in interview, the laboratory director failed to attest to the routine integration of PT samples into the patient workload for one of three PT events in 2026 (Event 1,2, and 3). Findings included: 1. Review of laboratory policy, "Proficiency Testing Policies" (Approved by the laboratory director in 2020) revealed the following: "...Thoroughly check all reported results for any clerical errors, and have the laboratory director sign the "Attestation Statement" on the PT "results" form." 2. Review of API PT records in 2026, revealed the laboratory director failed to document attestation of routine integration of PT samples into the patient workload for one of three PT events in 2026 (Event 3). 3. In an interview with testing person 1 (TP-1) on 09/14/2026 at 10:25 AM in the facility, TP-1 confirmed the laboratory director failed to attest to the routine integration of PT samples into the patient workload for one of three PT events in 2026 (Event 1,2, and 3).

D5401

PROCEDURE MANUAL
CFR(s): 493.1251(a)

(a) 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.

This STANDARD is not met as evidenced by:

Based on laboratory policy, patient test reports and confirmed in interview, the laboratory failed to follow its own policy for patient specimen processing for two of ten patients randomly reviewed in 2026. Findings included: 1. Review of laboratory policy, "Identify the Reference Ranges for your Practice" (Approved by the laboratory director on 06/2/2020) revealed the following acceptable reference range for Testosterone patient testing: Normal: 350-1000 Further review of laboratory policy revealed the following: "Procedures for Reporting Abnormal Results: Verbal notification followed by a retest." 2. Review of testosterone patient reports in 2026, revealed the following patients reported outside the range above: a. Patient 1 (Refer to Patient Alias List 1); Result: 1052 b. Patient 2 (Refer to Patient Alias List 1); Result: 1010 No documentation of retest for the above patients was provided. 3. In an interview with testing person 1 (TP-1) on 09/14/2026 at 10:35 AM in the facility, TP-1 confirmed the laboratory failed to follow its own policy for patient specimen processing for two of ten patients randomly reviewed in 2026.