

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D2126392	<b>(X3) Date Survey Completed</b> 04/28/2026
<b>Name of Provider or Supplier</b> Modern Male T Clinic - Cypress	<b>Street Address, City, State</b> 12361 Barker Cypress Road, Cypress, 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>	An announced survey of the laboratory was conducted on 04/28/2026. The laboratory was found in substantial compliance with applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories) for the specialties/subspecialties for which it was surveyed. STANDARD LEVEL DEFICIENCIES were cited.
<b>D5775</b>	<p>COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor's observations, review of laboratory's policies, records and staff interview, the laboratory failed to ensure twice annual instrument to instrument method comparison events met laboratory defined acceptability criteria for three of three evaluation events in 2025 and 2026. Findings included: 1. Surveyor's observations on 04/28/2026 at 0900 hours in the laboratory revealed the laboratory used two Qualigen FastPack IP System analyzers for testing testosterone levels. 2. Review of laboratory's policy "Testosterone Method Comparison" revealed: "POLICY: Verify that reportable results are comparable between analyzers that are in service. A random sample will be run on each analyzer that is in service every six months. The results must be within 10% (percent) of each other." 3. Review of laboratory's "Testosterone Method Comparison" records from 2025 and 2026 revealed the following three of three events did not meet the laboratory's acceptability criteria (results within 10% of each other): Event Date: 03/21/2025 Analyzer 0405 result: 376ng/dL (nanograms per deciliter) Analyzer 0853 result: 315ng/dL Percent difference:17.66% Event Date: 08/29/2025 Analyzer 0215 result: 1,019ng/dL Analyzer 0853 result: 913ng/dL Percent difference: 10.97 % Event Date: 03/06/2026</p>

Analyzer 0215 result: 703ng/dL Analyzer 0853 result: 537ng/dL Percent difference: 26.77% 4. In an interview on 04/28/2026 at 1100 hours in the breakroom, the laboratory's Technical Consultant number two (as indicated on submitted Form CMS 209) confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Services