

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D2279230	<b>(X3) Date Survey Completed</b> 01/08/2026
<b>Name of Provider or Supplier</b> Gameday Men's Health Austin	<b>Street Address, City, State</b> 2905 San Gabriel St Suite 310, Austin, 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 laboratory was found to be in compliance with 42 CFR Part 493, Requirements for Laboratories, as a result of a unannounced complaint (TX00557364) survey on January 8, 2026. The complaint was substantiated. Standard level deficiencies cited.
<b>D6015</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(4)</p> <p>(e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed and that--</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policy, the laboratory test menu, laboratory proficiency testing, and confirmed in interview, the laboratory director failed to ensure the laboratory was enrolled in proficiency testing (PT) for two of two moderate complexity tests performed by the laboratory in 2025. The findings included: 1. Review of the laboratory policy titled "Proficiency testing" included the following statement: "Purpose: To ensure a method is in place that is in accordance with Centers for Medicare and Medicaid Services (CMS) approved Proficiency Testing program for all regulated tests (analytes) performed in the laboratory." 2. Review of the laboratory test menu included the two following moderate complexity regulated analytes: Prostate Specific Antigen (PSA) Testosterone 3. Review of laboratory proficiency testing documentation did not include proficiency testing documentation for 2025. Surveyor asked for the documentation of enrollment for the PT 2025, and none could be provided. 4. In an interview on 01/08/2026 at 10:23 hours, in the laboratory, the general manager confirmed the laboratory, and laboratory director, had not ensured enrollment in an HHS approved PT program in 2025, for PSA and testosterone.</p>