

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D2297853	<b>(X3) Date Survey Completed</b>  12/12/2024
<b>Name of Provider or Supplier</b>  Gameday Men's Health - Mckinney	<b>Street Address, City, State</b>  1400 N Coit Road Suite 203, Mckinney, 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>D5785</b>	<p><b>CORRECTIVE ACTIONS</b> CFR(s): 493.1282(b)(3)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policy, review of temperature records from March 2024 to August 2024, and confirmed in interview, the laboratory failed to have documentation of performing corrective action for 10 of 88 days when temperature was documented outside the laboratory's acceptable range. Findings include: 1. Review of the laboratory's policy titled "Monitoring Laboratory Temperatures and Humidity" stated: "A. Temperature Monitoring 1. Refrigerator Acceptable Range 2 - 8C Corrective action must be taken when the internal temperature if outside the acceptable temperature range." 2. Review of the laboratory's temperature log documentation from March 2024 to August 2024 determined refrigerator temperatures were out-of-range on the following dates: a. March Day 11 Temperature: 0.8C Day 13 Temperature: 0.5C Day 15 Temperature: 0.5C Day 29 Temperature: 9.0C b. April Day 1 Temperature: 8.2C c. June Day 24 Temperature: 9.7C Day26 Temperature: 8.3 C d. July Day 8 Temperature: 8.9C e. August Day 23 Temperature: 8.2C Day 30 Temperature: 9.0C The laboratory was asked to provide documentation of performing corrective actions taken for when temperatures were outside the laboratory's acceptable range. No documentation was provided. 3. Testing person-2 (as listed on the CMS-209 form), confirmed the findings during an interview on 12/12/2024 at 1145 hours in the office. Key: CMS - Centers for Medicare and Medicaid Services</p>