Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D2287979	05/05/2026
Name of Provider or Supplier	**Street Address, City, State**	
Gd Stl Llc Dba Gameday Men's Health O'Fallon	856 Waterbury Falls Drive Ste 101, O Fallon, MO	

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 validation survey was performed on May 5, 2026, with the following standard level deficiencies cited.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the procedure manual, competency documentation, and interview with the laboratory owner, the laboratory failed to follow their policy and assess competency for one of one technical consultant (TC) in 2025. Findings included: 1. Review of the laboratory's procedure "Staff Orientation, Training, and Competency" stated, "The Lab Director is also responsible for ensuring that competency is assessed at least annually for the technical consultant, clinical consultant, and general supervisor." 2. Review of 2025 and 2026 competency documentation revealed the laboratory failed to perform an annual competency assessment for the TC in 2025. 3. Interview with the laboratory owner on May 5, 2026, at 4:00 PM, confirmed that the laboratory failed to follow written policies to assess the 2025 competency for the position of technical consultant. 4. The laboratory performs approximately 400 chemistry tests annually.
D5807	TEST REPORT CFR(s): 493.1291(d) (d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

	This STANDARD is not met as evidenced by: Based on a review of the laboratory procedure manual, two of two patient reports, and an interview with the laboratory staff, the laboratory failed to ensure the test report included pertinent reference intervals as determined by the laboratory. One of two chemistry analyte reference intervals listed on the patient's electronic medical record (EMR) report differed from those in the approved procedure manual. Findings included: 1. Review of the policy titled "Reference Ranges" showed "The following reference ranges have been obtained and validated and/or adjusted by the facility with signature of approval by Laboratory Director." Testosterone--Male 20-49 years: 214.1-1009.4 ng/dL Male >50 years: 216.2-1004.1 ng/dL 2. Review of two of two patient reports from the EMR revealed that the reference intervals for testosterone did not match the reference intervals in the procedure manual. EMR patient report: Testosterone--280-1200 ng/dL 3. Interview with the laboratory owner and testing personnel on May 5, 2026, at 4:00 PM confirmed that the laboratory failed to ensure the correct reference intervals approved in the procedure manual were included on the EMR patient report. 4. The laboratory performs approximately 200 testosterone tests annually.