Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D2321721	12/16/2025
Name of Provider or Supplier	**Street Address, City, State**	
Gameday Men's Health Hot Springs	2278 Albert Pike, Suite A, Hot Springs, AR	

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
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 the form CMS 209, laboratory policy and procedure, personnel records, lack of documentation, delegation of authority documents, and interview, the laboratory did not verify the competency of the Clinical Consultant (CC) on an annual basis. Findings follow: A) Review of the form CMS 209 provided by the laboratory on 12/16 /25 revealed that staff members (CC-1 as listed on form CMS 209) was identified as Clinical Consultant. B) Review of personnel records revealed that no competency as CC was provided for staff member (CC-1 on the form CMS 209). C) Upon request, the laboratory was unable to provide any competency assessments for the position of CC for the laboratory staff member (CC-1 on form CMS 209).
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

	This STANDARD is not met as evidenced by: Based upon observation, review of temperature records, lack of documentation and interview with laboratory staff, the laboratory failed to monitor the temperature on each day of operation in one of two rooms in which supplies with storage temperature requirements were stored. Findings follow: A) During a tour of the laboratory on 12/16 /25 at 9:50 a.m., the surveyor observed two rooms (laboratory room and phlebotomy room) containing laboratory items with a temperature storage requirement. B) A review of the laboratory's temperature records revealed that no room temperatures were recorded for the phlebotomy room for the calendar year 2025. C) During a tour of the laboratory on 12/16/25 at 09:15 a.m. the surveyor observed various BD Vacutainer SST Tubes with a storage temperature requirement of 2 degrees to 30 degrees Centigrade (C) in the phlebotomy room. D) Upon request, the laboratory could not present the temperature records for the phlebotomy room in which the supplies identified above were stored. E) In an interview on 12/16/25 at 9:35 a.m., Testing Personnel -1 listed on form CMS 209, confirmed that temperature records for the phlebotomy room were not recorded.
D5803	TEST REPORT CFR(s): 493.1291(b) (b) Test report information maintained as part of the patient's chart or medical record must be readily available to the laboratory and to CMS or a CMS agent upon request. This STANDARD is not met as evidenced by: A review of patient final reports, and interviews with laboratory staff, determined the laboratory failed to indicate the laboratory address for the in-house testing menu. As evidenced by: A. Upon reviewing a randomly selected patient final report for in house test menu for the following tests (Testosterone - Total, PSA - Total, Hemoglobin, and Hematocrit) no name and address of the laboratory location where the test was performed. B. In an interview on 12/16/2025 at 1:37pm, the testing personnel #1 (as listed on CMS form 209) confirmed the laboratory final report with no name and address of where the actual test was performed.
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 upon review of patient reports and interviews with laboratory staff the laboratory did not make a reference range for in house test menu for the following tests (Testosterone - Total, PSA - Total, Hemoglobin, and Hematocrit available to the individual responsible for using the test results. Findings follow: A) Review of the final report for in house test menu for the following tests (Testosterone - Total, PSA - Total, Hemoglobin, and Hematocrit) revealed that, under the heading "Reference Range", the report was blank and no reference range was given. B) In an interview on 12/16/25 at 2:10 p.m., Testing Personnel #1 (as listed on form CMS 209) confirmed that the reference range was not included on the reports, and that investigation of

	other in-house test menu for the following tests (Testosterone - Total, PSA - Total, Hemoglobin, and Hematocrit) showed that the reference range was not included.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based upon review of personnel files for Testing Personnel (TP) and Clinical Consultant (CC) listed on the form CMS-209, lack of documentation, and interviews with laboratory staff, the laboratory director failed to authorize two of two TP and one of one CC perform testing without direct supervision. Survey findings include: A) Review of personnel files for two TP listed and one CC on form CMS-209 (TP 's 1, 2, and CC-1) revealed no written authorization from the laboratory director to perform moderate complex testing without direct supervision was not present. B) In an interview, at 1:50 p.m. on 12/16/25 laboratory TP-1 confirmed the lack of written authorization to test for TP 's 1, 2, and CC-1 on form CMS 209.