Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D2322868	01/14/2026
Name of Provider or Supplier	**Street Address, City, State**	
Gameday Men's Health Burlington	3866 Rural Retreat Rd, Burlington, NC	

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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. In addition, retain the following: This STANDARD is not met as evidenced by: Based on review of 2025 Qualigen quality control records, the absence of records, and interview with TP (testing personnel) #1 on 1/14/26, the laboratory failed to retain quality control range cards for two lots of control material. Findings: Review of 2025 quality control records revealed the laboratory did not have control range cards for the following lot numbers of quality control material used for PSA (prostate specific antigen) and Testosterone testing on the Qualigen FastPack IP System: 1. Lot #2410004-2 2 Lot #2410004-4 During interview at approximately 2:50 p.m., TP #1 confirmed they did not have the control range cards for Lot #2410004-2 and Lot #2410004-4. TP #1 stated that Qualigen recently notified customers that they would no longer include printed assay range cards with quality control material and customers would have to print the assay ranges from a QR code provided by the manufacturer.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) (d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by:

	Based on review of manufacturer's instructions, review of the laboratory's policies and procedures, and interview with TP 1/14/26, the laboratory's procedures had not been signed and dated by the laboratory director to indicate review and approval. Review of the "Qualigen Diagnostics FastPack IP System Procedure Manual" revealed the manual had not been signed and dated by the laboratory director to indicate review and approval. Review of the "Qualigen Diagnostics FastPack IP System Quality Assurance Manual" revealed the manual had not been signed and dated by the laboratory director to indicate review and approval. Review of the manual revealed on page 6 "Personnel ... The Laboratory Director Confirms the Following: ... Procedure manuals are readily available to laboratory personnel at all times. These manuals have been signed and dated by the director at initial use and at any time procedures have been modified or updated. ..." At 1:27 p.m., the laboratory director sent an email to the surveyor with the PSA and Testosterone procedure attached. The procedure was for PSA and Testosterone using the NanoEntek FREND analyzer, not the Qualigen. The procedure was approved by the laboratory director 7/11/25. The laboratory director did not provide an approved procedure for PSA and Testosterone using the Qualigen FastPack IP System. During interview at approximately 1:40 p.m., TP #1 confirmed the manufacturer's procedure and quality assurance manuals had not been signed and dated by the laboratory director. TP #1 stated that the laboratory had planned to use the FREND analyzer, but it was never implemented.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and This STANDARD is not met as evidenced by: Based on review of the "Qualigen Diagnostics FastPack IP System Procedure Manual" and review of the laboratory's 2025 records 1/14/26, the laboratory director failed to ensure that verification methods were adequate to determine the accuracy, precision, and other performance specifications of the Qualigen FastPack IP System prior to use for patient PSA and Testosterone testing. Findings: Review of the "Qualigen Diagnostics FastPack IP System Procedure Manual" revealed on page 4 "Installation and Method Validation" instructions. The instructions stated that the method validation activities should be documented on worksheets provided by the manufacturer and found in the QA Log. The worksheets included blank spaces for the laboratory to document their information such as the values they obtained when performing testing for accuracy, precision, and reportable range. The worksheets had not been completed by the laboratory. Review of 2025 laboratory records revealed the laboratory had performed testing to verify the performance specifications of the PSA and Testosterone tests, but there was no documentation that the validation was reviewed and approved by the laboratory director prior to the start of patient testing, and it was not clear from the records the date that patient testing began.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;

	This STANDARD is not met as evidenced by: Based on review of the laboratory's 2025 quality control records and interview with TP #1 on 1/14/26, the laboratory director failed to ensure the establishment and maintenance of a quality control program to assure the ongoing quality of PSA and Testosterone testing performed on the Qualigen FastPack IP System. Findings: Review of the laboratory's quality control records revealed: 1. The laboratory had not maintained copies of control range cards for all lot number of control material used on the Qualigen FastPack IP System. See D3031 2. The laboratory's quality control records did not include the date that control material lot #2410004-6 was put into use. 3. The laboratory's quality control records did not indicate the lot number of Testosterone control material in use from 9/29/25-10/8/25, and from 10/25/25-12/31 /25. 4. In addition to the Qualigen control material, the laboratory used BioRad Liquichek Immunoassay Plus control material. During interview at approximately 2: 55 p.m., TP #1 stated they do not have a written procedure for use of the BioRad control material but the lab director requested they use it, and he lets them know if the results are acceptable.
D6061	CLINICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1419(c) (c) Ensure that reports of test results include pertinent information required for specific patient interpretation; and This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, review of the laboratory's test result form, observation, and interview with TP #1 on 1/14/26, the clinical consultant (laboratory director) failed to ensure that patient test reports included accurate information required for test result interpretation. Findings: Review of the "Qualigen Diagnostics FastPack IP System Quality Assurance Manual" revealed "Personnel ... The Laboratory Director Confirms the Following: ... Result reports include pertinent information required for interpretation. ..." Review of the "PATIENT LABORATORY RESULT FORM" used by the laboratory to report patient PSA and Testosterone test results revealed the form included the following: "These tests are performed by the FREND system which uses a quantitative immunoassay using microfluidic immunofluorescence. Values obtained with different assay methods should not be used interchangeably." During a tour of the laboratory at approximately 10:05 a.m., the surveyor observed the Qualigen FastPack IP System in use in the laboratory. During interview at approximately 2:25 p.m., TP #1 confirmed that the laboratory uses the Qualigen FastPack IP System for PSA and Testosterone testing. She stated they had planned to use the FREND, but it was never implemented.