Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2314813	04/09/2026
Name of Provider or Supplier	**Street Address, City, State**	
Blca Health Llc Dba Gameday Men's Health Laveen	7205 S 51st Ave Ste 201, Laveen, AZ	

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
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure manual, direct observation of patient specimens and interview with the laboratory director (LD) on 4/09/26 at 2: 18 PM, the laboratory failed to establish and follow written policies and procedures to ensure positive identification of patient specimens that were tested on the Frend Nano EnTek analyzer from 12/17/24 through 4/09/26. Findings include: 1. The laboratory began Testosterone and Prostate-Specific Antigen (PSA) testing on 12/17/24 on the Frend Nano EnTek analyzer in the subspecialties of routine chemistry and endocrinology with a reported annual test volume of 500. 2. Direct observation of patients' blood specimens on 4/09/26 revealed the testing personnel labeled the specimens with the only the first name and the initial of the last name. No other patient identifiers were documented on the specimen labels. 3. The laboratory failed to establish a written policy and procedure to ensure positive patient identification of blood specimens tested for Testosterone and PSA on the Frend Nano EnTek analyzer from 12/17/24 through 4/09/26. 4. LD interviewed on 4/09/26 at 2:18 PM confirmed the laboratory failed to provide evidence of an established policy and procedure to ensure positive identification of patient specimens tested on the Frend Nano EnTek analyzer as indicated above.
D5301	TEST REQUEST CFR(s): 493.1241(a)

	(a) The laboratory must have a written or electronic request for patient testing from an authorized person. This STANDARD is not met as evidenced by: Based on review of test requisition documentation and interview with the laboratory director (LD) on 4/09/26 at 2:20 PM, the laboratory failed to have a written or electronic request for Testosterone and Prostate-specific Antigen (PSA) testing performed on the Frend Nano EnTek analyzer for 1 out of 4 patient records reviewed. Findings include: 1. No written or electronic request for Testosterone and PSA testing was presented for review for 1 out of 4 patient records reviewed during the survey (record #2). 2. LD interviewed on 4/09/26 at 2:20 PM confirmed the laboratory failed to have an electronic or written test requisition for Testosterone and PSA testing as indicated above. 3. The laboratory began Testosterone and Prostate-Specific Antigen (PSA) testing on 12/17/24 on the Frend Nano EnTek analyzer in the subspecialties of routine chemistry and endocrinology with a reported annual test volume of 500.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual for Testosterone and Prostate-specific Antigen (PSA) testing, review of patient test results maintained in the electronic medical record (EMR) and interview with the laboratory director (LD) on 4 /09/26 at 2:20 PM, the test procedures for Testosterone and PSA failed to include the laboratory's system for entering and reporting patient test results in the EMR. Findings include: 1. The laboratory began Testosterone and Prostate-Specific Antigen (PSA) testing on 12/17/24 on the Frend Nano EnTek analyzer in the subspecialties of routine chemistry and endocrinology with a reported annual test volume of 500. 2. The laboratory director interviewed on 4/09/26 at 2:20 PM stated that the medical assistant's should be manually entering test results into the EMR on a lab report form that is maintained in the EMR. 3. Review of patient test results in the EMR revealed 1 out of 4 records reviewed (record #2) failed to include the PSA and Testosterone test

	results on a lab report form. The test results were manually entered in the patient's visit note, but no lab report form was located in the EMR. 4. The test procedures reviewed for Testosterone and PSA testing failed to include information about the laboratory's system for entering and reporting test results in the EMR. 5. LD interviewed on 4/09/26 at 2:20 PM confirmed the Testosterone and PSA test procedures lacked information regarding the laboratory's system for entering and reporting patient test results in the EMR.
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 on review of the laboratory's temperature and humidity records, review of the manufacturer's environmental specifications for the Frend Nano EnTek analyzer, direct observation of the temperature measuring device located in the laboratory and interview with the laboratory director on 4/09/26 at 3:00 PM, (A) the laboratory failed to define a room temperature range consistent with the manufacturer's requirements from May 2025 - February 2026; and (B) failed to accurately record humidity measurements of the laboratory on 57 out of 57 testing dates from 10/20/25 through 2 /27/26. Findings include: 1. The laboratory began Testosterone and Prostate-Specific Antigen (PSA) testing on 12/17/24 on the Frend Nano EnTek analyzer in the subspecialties of routine chemistry and endocrinology with a reported annual test volume of 500. A2. The manufacturer's environmental specifications for the Frend analyzer state, "Assure the room temperature is in the range of 64-77 F (18-25C) when tests are run." A3. Review of the laboratory's room temperature records from May 2025 - August 2025 indicated a room temperature range of 59-88 F, and a room temperature range of 59-80 F from September 2025 - February 2026. A4. The laboratory's range for room temperature failed to align with the manufacturer's requirement of 64-77 F from May 2025 - February 2026, as indicated above. A5. The LD interviewed on 4/09/26 at 3:00 PM acknowledged that the room temperature range listed on the temperature logs from May 2025 - February 2026 was not consistent with the room temperature requirement set forth by the manufacturer of the Frend Nano EnTek analyzer. B1. Review of the laboratory's humidity measurements indicated the laboratory recorded the room temperature measurement rather than the humidity measurement on 57 out of 57 testing dates from 10/20/25 through 2/27/26. B2. Direct observation of the room temperature/hygrometer measuring device revealed buttons on the device that can toggle between the room temperature readings and humidity readings. At the time of the survey, the device was showing only the room temperature measurement and that value was being recorded as the humidity measurement. B3. The LD interviewed on 4/09/26 at 3:00 PM confirmed laboratory personnel were recording the room temperature values as the humidity measurement on the laboratory's temperature logs from 10/20/25 through 2/27/26.

D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the laboratory's temperature records and interview with the Laboratory Director (LD) on 4/09/26 at 3:00 PM, the laboratory failed to document corrective action that was taken for room temperature measurements that were outside the manufacturer's specified range for 17 out of 91 testing dates from June 2025 through November 2025. Findings include: 1. The laboratory began Testosterone and Prostate-Specific Antigen (PSA) testing on 12/17/24 on the Frend Nano EnTek analyzer in the subspecialties of routine chemistry and endocrinology with a reported annual test volume of 500. 2. The laboratory's listed range for room temperature failed to align with the manufacturer's requirement of 64-77 F from May 2025 - February 2026. The room temperature range listed on the laboratory's temperature log was 59-88 F. See D5413 for findings. 3. Review of the monthly temperature logs from June through November 2025 revealed the documented room temperature measurement exceeded the manufacturer's room temperature requirement of 77 F on 17 out of 91 testing dates. 4. The laboratory failed to document corrective action taken for the room temperature measurements that were outside the manufacturer's required range on the 17 testing dates indicated above. 5. LD interviewed on 4/09/26 at 3:00 PM confirmed the laboratory failed to document corrective action for room temperature measurements that exceeded the manufacturer's required range of 64-77 F for the 17 testing dates indicated above.