| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 05D2151482 | 06/17/2019 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Gameday Men's Health | 2333 State Street, Suite 200, Carlsbad, CA | |

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 |
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| **D5421** | ESTABLISHMENT AND VERIFICATION OF PERFORMANCE<br>CFR(s): 493.1253(b)(1)<br><br>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory validation records, and interview with the technical consultant (TC), it was determined that the laboratory failed to follow the CLIA regulations to perform acceptable validations for Qualigen FastPack analyzer, a FDA unmodified test system including 1) Accuracy, 2) Precision, 3) Reportable range, 4) Reference intervals. The findings included: a. The laboratory used Qualigen FastPack test system to perform and report serum PSA, Testosterone (TST) and manage the client health outcomes. b. The laboratory failed to follow CLIA requirements to perform, evaluate and document the acceptable performances specifications of FastPack test system for 1) Accuracy, 2) Precision, 3) Reportable range, and 4) Reference intervals. c. For reference intervals of TST between 23 and 1,600 ng/dL, the laboratory must provide supporting data and records to assure the establishment. d. The laboratory must provide valid and acceptable verification of TST testing system following the CLIA regulation 42 CFR part 493. 1253 (b) (1) Verification of Performance Specifications. |
| **D5439** | CALIBRATION AND CALIBRATION VERIFICATION<br>CFR(s): 493.1255(b) |

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| | Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation of the laboratory supplies and operations, review of the laboratory records, verified the laboratory calibrators and quality control materials, and interview with the technical consultant (TC), it was determined that the laboratory failed to follow the CLIA regulations to perform calibration verification (CV) and document the data to verify the reportable range for the testing results. The findings included: a. The laboratory used Qualigen FastPack test system to perform serum PSA and TST. b. Qualigen FastPack provides 2 calibrator materials (C1 & C2) for PSA and one calibrator for TST in FastPack testing system. c. A calibration verification must be performed and documented, at least every 6 months when a testing system used less than three calibrators (a minimal or zero) value, a mid-point value, and a maximum value near the upper limit of the reportable range. d. The laboratory failed to perform calibration verification at least very 6 months. e. The laboratory must provide document for the establishment of its TST reference intervals between 23 to 1,600 ng/dL to reflect the client population. See D-5421 |
| **D5807** | TEST REPORT<br>CFR(s): 493.1291(d)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation of the laboratory supplies, review of the laboratory test result reports and records, and interview with the technical consultant (TC), it was determined that the laboratory failed to ensure that the reference interval (normal value) it provided to the clients was pertinent, accurate and reflect the method performed and the client populations. The findings included: a. The laboratory used Qualigen FastPack system to perform serum Testosterone (TST). b. The laboratory must provide pertinent reference interval (value) for its TST test result. c. The reports |

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| | indicated that the reference interval (value) for TST between 23 and 1,600 ng/dL, which may not be pertinent. d. The establishment of its reference must be supported by the laboratory's validation of the test system before implement the testing procedure. See D-5421 e. The laboratory must verify its calibration verification at least 6 months to ensure the reportable range is valid. See D-5439 |
| **D6021** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(5)<br><br>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation of the laboratory supplies and operations, review of the laboratory records, verified the laboratory calibrators and quality control materials, and interview with the technical consultant (TC), it was determined that the laboratory director failed to be responsible for the overall operation and ensure that quality assessment programs to verify the verification of performance specifications and calibration verification were performed and documented before releasing the patient test reports to maintain and assure the quality of laboratory services provided. The findings included: a. The laboratory failed to perform verification of performance specification of TST. See D-5421 b. The laboratory failed to perform calibration verification for both of TST and PSA. See D-5439. |
| **D6026** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(8)<br><br>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(8) Ensure that reports of test results include pertinent information required for interpretation.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation of the laboratory supplies and operations, review of the laboratory records, verified the laboratory calibrators and quality control materials, and interview with the technical consultant (TC), it was determined that the laboratory director failed to be responsible for the overall operation and ensure that reports of test results include pertinent information required for interpretation. The findings included: a. The laboratory performed serum TST with a reference interval (values) between 23 and 1,600 ng/dL, which may not be pertinent. See D-5421 and D-5807 |