Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D2290564	(X3) Date Survey Completed 09/13/2024
Name of Provider or Supplier Wellness Club, The	**Street Address, City, State** 2194 Snake River Pkwy Ste 103, Idaho Falls, ID	

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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on a lack of proficiency testing (PT) records and an interview with testing personnel 1 (TP1) on 9/13/2024, the laboratory failed to enroll in proficiency testing since opening on 10/01/2023. The findings include: 1. A lack of PT records identified that the laboratory failed to enroll and participate in PT for all analytes performed by the laboratory since opening on 10/01/2023. The analytes include: prostate specific antigen and total testosterone. 2. An interview with TP1 on 9/13/2024 at 9:13 am confirmed that the laboratory failed to enroll and participate in PT for all analytes since opening on 10/01/2023. 3. The laboratory projects performing 300 tests annually.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: (1) Water quality. (2) Temperature. (3) Humidity. (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 a lack of laboratory temperature logs and an interview with testing personnel 1 (TP1) on 9/13/2024, the laboratory failed to establish and monitor the testing temperature and humidity and storage temperature for reagents since opening on 10/01/2023. The findings include: 1. A lack of the laboratory temperature logs identified the laboratory failed to establish and monitor testing temperature and humidity per the NanoEntek FREND manufacturer requirements. 2. A lack of the laboratory temperature logs identified the laboratory failed to establish and monitor reagent storage temperature per the NanoEntek FREND manufacturer requirements. 3. An interview with TP1 on 9/13/2024 at 9:13 am confirmed that the laboratory failed to monitor temperatures and humidity since opening on 10/01/2023. 4. The laboratory projects performing 300 tests annually.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on a review of instrument manuals, a lack of maintenance logs and an interview with testing personnel 1 (TP1) on 9/13/2024, the laboratory failed to perform function checks as required by the NanoEntek FREND manufacturer. The findings include: 1. A review of the NanoEntek FREND user manual identified that the Q.C. Check is to be performed daily to verify the performance of the analyzer. 2. A lack of maintenance logs for the NanoEntek FREND identified that the laboratory failed to perform the required performance verification using the Q.C. Check daily since opening in 10/01/2023. 3. An interview with TP1 on 9/13/2024 at 9:10 am confirmed the above finding. 4. The laboratory projects performing 300 tests annually.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a lack of Quality Control (QC) records and an interview with testing personnel 1 (TP1) on 9/13/2024, the laboratory failed to successfully perform two levels of QC each day of use on the NanoEntek FREND since opening on 10/01/2023. The findings include: 1. A lack of QC documents for the NanoEntek FREND for 2023

	and 2024 identified that the laboratory failed to perform two levels of external QC for each analyte everyday of testing in 2023 and 2024. 2. An interview with TP1 on 9/13 /2024 at 9:10 am confirmed the above finding. 3. The laboratory projects performing 300 tests annually.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid (CMS) personnel form 209, lack of Proficiency Testing (PT) documents, a lack of documentation, and an interview with testing personnel 1 on 9/13/2024, the laboratory director failed to ensure that new instrument verifications were performed, that testing personnel had training and were competent to provide accurate and reliable patient results, that PT was ordered and performed, that testing personnel had policies and procedures to follow, and that the laboratory had a quality assurance plan. See D6013, D6015, D6120, D6121, D6129 and D6131.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on a review of the NanoEntek FREND instrument verification and an interview with testing personnel 1 (TP1) on 9/13/2024, the laboratory director failed to ensure that the verification of instrument performance specifications were adequate. The findings include: 1. A review of the new instrument verification of the NanoEntek FREND identified that the laboratory director failed to review and approve the verification results for accuracy, precision, and reportable range to ensure that they were adequate before beginning patient testing. 2. An interview with TP1 on 9/13 /2024 at 8:44 am confirmed that the laboratory director failed to review and approve the verification. 3. The laboratory projects performing 300 tests annually.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on a lack of Proficiency Testing (PT) records and an interview with testing personnel 1 (TP1) on 9/13/2024, the laboratory director failed to ensure that the laboratory was enrolled in PT for all testing performed since opening on 10/01/2024. The findings include: 1. A lack of PT records identified that the laboratory failed to enroll and participate in PT for prostate specific antigen and total testosterone. See D2000 2. An interview with TP1 on 9/13/2024 at 9:13 am confirmed the above finding. 3. The laboratory projects performing 300 tests annually.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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 the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a lack of quality control (QC) documentation and an interview with testing personnel 1 (TP1) on 9/13/2024, the laboratory director failed to ensure that the laboratory had an acceptable QC plan that testing personnel were following. The findings include: 1. A lack of a QC policy and QC documentation for prostate specific antigen (PSA) and total testosterone testing identified that the laboratory failed to perform and document acceptable QC since opening on 10/01/2023. See D5447 2. An interview with TP1 on 9/13/2024 at 9:10 am confirmed the above finding. 3. The laboratory projects performing 300 tests annually.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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. This STANDARD is not met as evidenced by: Based on a lack of laboratory policies and procedures and an interview with testing personnel 1 (TP1) on 9/13/2024, the laboratory director failed to establish a quality assurance (QA) plan for the laboratory to follow. The findings include: 1. A lack of laboratory policies and procedures identified that the laboratory failed to establish and follow a QA plan for general laboratory systems that included assessing specimen identification and integrity, personnel competencies and proficiency testing performance. 2. A lack of laboratory policies and procedures identified that the

	laboratory failed to establish and follow a QA plan for preanalytic laboratory systems that included assessing specimen handling and collection problems, and inadequate specimen preparation. 3. A lack of laboratory policies identified that the laboratory failed to establish a QA policy for analytic systems to monitor and assess test procedures, equipment maintenance, verification of method performance, calibration verification, control procedures and corrective actions. 4. A lack of laboratory policies and procedures identified that the laboratory failed to establish and follow a QA plan for post analytic laboratory systems that included assessing test reports, laboratory turn around times, calculated data, and accurate patient information. 5. An interview with TP1 on 9/13/2024 at 8:57 am confirmed that they failed to have a QA plan. 6. The laboratory projects performing 300 tests annually.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, a lack of documentation, an interview with testing personnel 1 (TP1) on 9/13/2024, the laboratory director failed to ensure that one of one testing personnel had the training to accurately perform and report patient testing. The findings include: 1. A review of the CMS 209 identified one testing personnel. 2. A lack of training documentation identified that the laboratory failed to have documentation of initial training for one of one testing personnel performing testing on the NanoEntek FREND before beginning patient testing. 3. An interview with TP1 on 9/13/2024 at 8: 54 am confirmed that there was no documentation of training. 4. The laboratory projects performing 300 tests annually.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by:

	Based on a review of the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, laboratory policies and procedures, a lack of documentation, an interview with testing personnel 1 (TP1) on 9/13/2024, the laboratory director failed to ensure that there was a policy for performing competency assessments to ensure that testing personnel accurately performed and reported patient testing. The findings include: 1. A review of the CMS 209 identified one testing personnel. 2. A lack of policies and procedures identified that the laboratory director failed to establish a policy to ensure competency assessments were performed on testing personnel. 3. A lack of competency assessment documentation identified that the laboratory failed to have documentation of six month competency for one of one testing personnel performing testing on the NanoEntek FREND. 4. An interview with TP1 on 9/13/2024 at 8:54 am confirmed the above findings. 5. The laboratory projects performing 300 tests annually.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on review of laboratory documents, a lack of a policy and procedure manual and an interview with testing personnel 1 (TP1) on 9/13/2024, the laboratory director (LD) failed to ensure that there was a laboratory policy and procedure manual for testing personnel to follow. The findings include: 1. A review of laboratory documents and a lack of a policy and procedure manual identified that the LD failed to ensure an approved procedure manual that included but was not limited to procedures for testing, competency assessments, proficiency testing, quality assurance, specimen collection and rejection, quality control performance and critical values was available for testing personnel to follow. 2. An interview with TP1 on 9/11 /2024 at 8:57 am confirmed that the LD failed to ensure that there was an approved procedure manual for personnel to follow. 3. The laboratory projects performing 300 tests annually.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, educational documents and an interview with the laboratory director on 9/13/2024, the laboratory failed to have a technical consultant that qualified with the minimum educational and experience requirements. See D6035

D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, educational documents and an interview with the laboratory director on 9/13/2024, the laboratory failed to have a qualified technical consultant since opening on 10/01/2024. The findings include: 1. A review of educational documents for the personnel listed on the CMS 209 identified that the laboratory failed to hire a technical consultant with a bachelor's degree or higher in chemical, physical, biological science or medical technology with the required testing experience. 2. An interview with the laboratory director on 9/13/2024 at 9:36 am confirmed that the laboratory failed to have a qualified technical consultant. 3. The laboratory projects performing 300 tests annually.