

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2011573	(X3) Date Survey Completed 10/14/2021
Name of Provider or Supplier Sun Wellness Llc	Street Address, City, State 2273 Route 33, Golden Crest, Hamilton, NJ	
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
D5221	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Laboratory Director (LD) the laboratory failed to review and evaluate results when they received an unacceptable score in FreeTriiodothyronine (T3) performed with the American Proficiency Institute (API) for the 2021 Chemistry Core Third Event. The findings include: 1. The laboratory received an 50% Grade for Free T3. 2. There was no documented evidence that the laboratory investigated the failure. 3. The LD confirmed on 10/14/21 at 10:30 am that the laboratory did not review and document an evaluation of unacceptable PT results.</p>
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM) and interview with the Laboratory Director (LD) , the laboratory failed to have an approved, signed and dated PM by the LD from January 2020 to the date of the survey. The LD confirmed on 10/14/21 at 12:30 pm a PM signed by the LD was not available.</p>
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p>

Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

This STANDARD is not met as evidenced by:

Based on surveyor observation of the controls in use, review of the Manufacturers Package Insert (MPI) and interview with the Laboratory Director (LD), the laboratory failed to follow MPI for controls at the time of the survey. The finding includes: 1. Controls in use did not have an open or expiration date documented as per MPI. Controls in use were Biorad Lyphocheck Specialty Immunoassay lot numbers 25301 and 25303. (expiration date 1/31/2023) 2. The LD confirmed on 10/14/21 at 11:30 am that MPI was not followed. Note: This is a repeat citation. It was previously cited on 8/9/18. Plan of Correction stated: "The control bottle will be labeled with the date of opening and expiration."

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 surveyor review of Temperature Records (TR) and interview with the Laboratory Director (LD), the laboratory failed to monitor and record the temperature of the refrigerator and room where Tosoh A1A reagents, controls and calibrators were stored from 8/9/18 to the date of the survey. The finding includes: 1. A review of the TR revealed temperature was taken twice a month when testing was performed.. 2. The LD confirmed on 10/14/21 at 12:15 pm that room and refrigerator temperature were not monitored and recorded. Note: This is a repeat citation. It was previously cited on 8/9/19. Plan of Correction Stated: "Room, temperature, humidity, freezer and refrigerator temperature will be documented for the days when no tests are performed."

D5415

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(c)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:

Based on surveyor observation of reagents, solutions, review of the Manufacturers Package Insert (MPI) and interview with the Laboratory Director (LD), the laboratory failed to put prepared and expiration dates on the reagents and solutions used to perform Chemistry and Endocrinology tests at the time of the of survey. The findings include: 1. The Tosoh AIA 900 MPI stated that the working diluent and wash solution were stable for 30 days at Room Temperature. 2. The laboratory did not put a prepared and expiration date on the working diluent and wash solution in use. 3. The LD confirmed on 10/14/21 at 9:45 am the laboratory failed to label the working diluent and wash solution. Note: This is a repeat citation It was previously cited on 8/9 /18. Plan of Correction stated: "All reagents bottles will be labeled in the future."

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:
a) Based on surveyor review of the reagents, calibrators and interview with the Laboratory Director, the laboratory had expired material for Routine Chemistry and Endocrinology tests performed on the Tosoh A1A 900 analyzer from 8/9/18 to the date of survey. The findings include: 1. ST A1A- Pack Follicle Stimulating Hormone (FSH) Lot A916803 expired 8/31/21 2. Approximately 45 patients were run with the expired reagent. 3. The LD confirmed on 10/14/21 at 12:45 pm that the laboratory had an expired reagent. b) Based on surveyor review of the Quality Control (QC) records and interview with the LD, the laboratory used expired QC material for Chemistry and Endocrinology tests performed on the Tosoh A1A 900 analyzer from 1/11/20 to 3/21 /20. The findings include: 1.. LChek Lot 40951 and LChek Lot 40952 expired on 10 /31/19. 2. Approximately 80 patients were run with the expired QC. 3. The LD confirmed on 10/14/21 at 1:00 pm that the laboratory used expired QC material. Note: This is a repeat citation. It was cited on 8/9/18 and 7/20/17. Plan of Correction stated: "Sun Wellness LLC upholds a high standard in laboratory testing and does not use expired reagents."

D5469

CONTROL PROCEDURES
CFR(s): 493.1256(d)(10)(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-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

	<p>This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records and interview with the Laboratory Director (LD), the laboratory failed to verify that the assayed QC material for all tests performed on Tosoh A1A 900 analyzer before they were put into use from 8/9/18 to the date of survey. The LD confirmed on 10/14/21 at 11:45 am that the laboratory failed to verify the QC material before use. Controls in use were Biorad Lyphocheck Specialty Immunoassay lot numbers 25301 and 25303. (expiration date 1/31/2023) Note: This is a repeat deficiency. it was cited on 8/9/17 and 7/20/17. Plan of Correction stated: "This issue was addressed in 2017. Any new QC material will be verified before it's put into use when current lot of QC material expires."</p>
<p>D5805</p>	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Final Report (FR) and interview with the Laboratory Director (LD), the laboratory failed to ensure that the FR included all the required information for Chemistry and Endocrinology tests from 8/9/18 to the date of survey. The finding includes: 1. The FR did not have the correct specimen time for sample ID number 81375350 on 6/8/20. It stated time of sample collection as 12:00 am 2. The LD confirmed on 10/14/21 at 11:00 am that the FR failed to include the correct time of sample collection.</p>
<p>D5807</p>	<p>TEST REPORT CFR(s): 493.1291(d)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Final Report (FR), Manufacturer Package Insert (MPI) and interview with the Laboratory Director(LD), the laboratory failed to identify the source of the Reference Intervals (RI) used for Testosterone tests on the Tosoh A1A 900 analyzer from 8/9/18 to the date of survey. The findings include: 1. The MPI RI for Testosterone was 199-1586 ng/dl but the FR RI was 350-1586. 2 The LD confirmed on 10/14/21 at 12:45 pm that the RI on the FR was not that of the RI in the MPI. Note: This was previously cited on 7/20/17</p>
<p>D6013</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii)</p>

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 surveyor review of the Performance Specification (PS) records and interview with the Laboratory Director (LD), the LD failed to ensure that PS procedures performed on the Tosoh AIA 900 analyzer were adequate from 8/9/18 to the date of survey. The findings include: 1. The LD did not review and sign the PS results. 2. A Method Comparison was not performed 3. The LD confirmed on 10/14/21 at 12:30 pm that PS records were not adequate.

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 surveyor review of the Quality Control (QC) records and interview with the Laboratory Director (LD), the LD failed to ensure that the QC program is maintained for laboratory services provided from 8/9/18 to the date of the survey. The findings include: 1. Tosoh AIA controls were not verified before putting in use. 2. There was no monthly QC available to review. 3. The LD confirmed 9/14/21 at 10:50 AM the LD did not ensure the QC plan was maintained. .

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 the surveyor review of the Quality Assessment (QA) policy and interview with the Laboratory Director (LD), the LD failed to ensure that the QA program was maintained from 8/9/18 to the date of survey. The findings include: 1. The QA program stated monthly reviews should be done for Quality Control (QC) but there was no documented evidence a QA review was performed. 2. The QA program stated

monthly reviews should be done for Patient Test Management and Instrument Performance, Maintenance and Test Calibration. There was no documented evidence that a QA review was performed 3. The LD confirmed on 10/14/21 at 12:45 pm that the QA reviews were not performed.

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 surveyor review of the Personnel Files (PF) and interview with the Laboratory Director (LD) , the LD failed to have appropriate training documentation for the TP performing laboratory testing from 8/9/18 to the date of survey. The finding includes: 1. The laboratory did not have training records for the Tosoh A1A 900 2. The LD confirmed on 10/14/21 at 12:00 pm the above records were not on file.

D6074

TESTING PERSONNEL RESPONSIBILITIES

CFR(s): 493.1425(b)(5)

Each individual performing moderate complexity testing must be capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the technical consultant, clinical consultant or director.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Quality Control (QC) records and interview with the Laboratory Director (LD), the TP failed to identify problems that may affect test performance by not reviewing and evaluating trends and/or shifts for tests performed on the Tosoh A1A 900 analyzer from 8/9/18 to the date of survey. The LD confirmed on 10/14/21 at 12:00 pm that trends and shifts were not reviewed.