

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2011573	(X3) Date Survey Completed 08/09/2018
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
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</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 Chemistry PT results obtained from the American Proficiency Institute (API) performed in the calendar years 2017 and 2018. The finding includes: 1. There was no review or evaluation documented for Chemistry Core events 1 and 3-2017 and 2-2018. 2. There was no review or evaluation documented for Chemistry Miscellaneous events 1-2017 and 1-2018. 3. The LD confirmed on 8/9/18 at 12:40 pm the laboratory did not review all PT results. .</p>
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyors observation of the Manufacturers Instruction (MI) for controls in use and interview with the Laboratory Director (LD), the laboratory failed to follow</p>

	<p>MI 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 MI. 2. The LD confirmed on 8/9/18 at 1:15 pm that MI were not followed.</p>
<p>D5413</p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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.</p> <p>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 7/20/17 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 8/9/18 at 12:50 pm that room and refrigerator temperature was not monitored and recorded.</p>
<p>D5415</p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: a) Based on surveyor observation of reagents, solutions 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 600 II Manufacturers Package Insert 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 8/9/18 at 12:30 pm the laboratory failed to label the working diluent and wash solution. b) Based on surveyor observation of the refrigerated reagents and interview with the LD, the laboratory failed to label all the reagents used to perform Chemistry and Endocrinology tests with pertinent information at the time of the survey. The finding includes: 1. A 50 ml reagent vial found in the refrigerator was not labeled with its identity, strength or concentration, storage requirements, preparation and expiration date. 2. The LD confirmed on 8/9/18 at 1:45 pm the reagent vial was not labeled.</p>
<p>D5417</p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p>

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:

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 analyzer from January 2017 to the date of survey. The findings include: 1. Calibrators and Reagents were expired as follows: a. Sex Hormone-Binding Globulin (SHBG) Sample Diluent - Lot F85C405 expired August 2016 b. ST A1A Pack Program II - Lot H83C718 expired 7/31/18 c. A1A Pack Prostate Specific Antigen (PA) Calibrator - Lot H831222 expired 7/31/18 d. A1A Pack Prolactin (PRL) Calibrator - Lot H833124 expired 7/31/18 e. A1A Pack Progesterone (PR-2) Calibrator - Lot F15C701 expired January 2016 f. Ferritin Cal Verification Lot G300386 expired March 2017 g. PA Cal Verification Lot G301290 expired 3/31/17 h. PRL Cal Verification Lot G103181 expired January 2017 i. Follicle Stimulating Hormone (FSH) Cal Verification Lot G103384 expired January 2017 2. Approximately 15 patients were run twice a month. 3. The LD confirmed on 8/9/18 at 1:00 pm that the laboratory had expired reagents and calibrator material.

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(1)

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.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Final Reports (FR) and interview with the Laboratory Director (LD), the laboratory failed to have verification for the Reference Intervals (RI) used for 13 out of 15 tests performed on Tosoh A1A analyzer from 7/20 /17 to the date of the survey. The LD confirmed on 8/9/18 at 2:25 pm that she did not have verification of RI.

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.

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 assayed QC materials were within the acceptable ranges before they were put into use for Chemistry and Endocrinology Testing on the Tosoh A1A 600 II analyzer from 7/20/17 to the date of survey. The findings include: 1. This was cited on the previous survey performed on 7/20/17. 2. The Plan of Correction (POC) received for the 7/20/17 survey stated "In the future, any new QC material will be verified before it is put into use when the current lot of QC needs to be replaced." 3. The LD confirmed on 8/9/18 at 2:15 pm that the laboratory did not verify QC material and follow POC. .

D5479

CONTROL PROCEDURES
CFR(s): 493.1256(e)(5)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on surveyors observation of controls in use and interview with the Laboratory Director (LD), the laboratory failed to follow Manufacturers Specifications (MS) 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 MS. 2. The LD confirmed on 8/9/18 at 1:15 pm that MS were not followed.

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 surveyor review of the work records and interview with the Laboratory Director (LD), the laboratory did not document corrective action taken when Endocrinology and Chemistry calibration expired on the Tosoh A1A in March and July 2018. The findings include: 1. On 3/10/18 Insulin Control 1 & 2 were flagged with CV (calibration void/expired) and the calibration record showed it wasn't calibrated until 4/7/18. 2. A review of records showed 11 patients were run on 3/10/18

and 14 on 3/11/18. 3. On 7/14/18 Progesterone 2 (PR2) Control 1 was flagged with CV. 4. A review of records showed 14 patients were run on 7/14/18. 5. The LD confirmed on 8/9/18 at 2:20 pm that corrective action was not documented on expired calibrations.

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 surveyor review of the Procedure Manual (PM) and interview with the Laboratory Director (LD), the LD failed to ensure that a PM was available for Chemistry and Endocrinology testing from 7/20/17 to the date of the survey. The finding includes: 1. The procedures found in the PM had a Lawrenceville address. 2. The LD confirmed on 8/9/18 at 3:00 pm a PM was not available with the Hamilton address.

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 LD failed to identify problems that may affect test performance by not reviewing and evaluating trends and/or shifts for Routine Chemistry and Endocrinology tests performed on the Tosoh A1A 7/20/17 to the date of the survey. The LD confirmed on 8/9/18 at 2:45 pm that trends and shifts were not reviewed.