

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2011573	(X3) Date Survey Completed 06/29/2023
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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: A) Based on surveyor review of the Procedure Manual (PM), and interview with the Laboratory Director (LD), the laboratory failed to follow all procedures written for "Procedure Manual Review" from 2/19/19 to the date of the survey. The findings include: 1. The procedure "Procedure Manual Review" stated "Annually, the Lab Director will review all policies and procedures and ensure that all lab staff has reviewed all policies and procedures. These reviews will be documented by signature and date on an attestation page at the front of the Procedure Manual." 2. There was no documented evidence the above mentioned procedure was performed. 3. The LD confirmed on 6/29/23 at 11:00 am that the PM was not followed. B) Based on surveyor review of the Procedure Manual (PM), and interview with the Laboratory Director (LD), the procedures in the PM did not reflect the current instrumentation in use. The findings include: 1. The laboratory is currently using the Tosoh AIA 900 but all procedures in the PM were specified for the Tosoh AIA 600 II. 2. The LD The LD confirmed on 6/29/23 at 11:00 am that the PM does not reflect the current instrumentation in use.</p>
D5409	<p>PROCEDURE MANUAL CFR(s): 493.1251(e)</p> <p>The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2).</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 record discontinuance dates for procedures not performed in the laboratory on the date of survey. The finding includes: 1. There were no discontinuance dates for the Vitamin B12 and Folate procedures in the PM. 2. There were no discontinuance dates for procedures for the Tosoh AIA 600 II analyzer in the PM. 3. The LD confirmed on 6/29/23 at 11:30am the laboratory failed to record discontinuance dates on the above mentioned procedures in the PM.

D5411

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

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 quality controls (QC) in use, review of the Manufacturers Package Insert (MPI) and interview with the Laboratory Director (LD), the laboratory failed to follow the QC MPI at the time of the survey. The finding includes: 1. Controls in use did not have an open or expiration date documented as per the MPI. QC in use were Biorad Lyphocheck Specialty Immunoassay lot numbers 88733 and 88731 and Biorad Liquichek lot numbers 85331 and 85333. 2. The LD confirmed on 10/14/21 at 11:30 am the laboratory failed to follow the MPI for the above mentioned QC in use. Note: This is a repeat citation. It was previously cited on 8/9/18 and 10/14/21. Plan of Correction stated: "The control bottle will be labeled with the date of opening and expiration."

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 and interview with the Laboratory Director (LD), the laboratory failed to put expiration dates on the reagents and solutions used to perform Chemistry and Endocrinology tests at the time of the survey. The findings include: 1. The Tosoh AIA 900 Manufacturers Package Insert (MPI) stated that the working diluent and wash solution were stable for 30 days at Room Temperature. 2. The laboratory did not put an expiration date on the working diluent and wash solution in use. 3. The LD confirmed on 6/29/23 at 12:30 pm the laboratory failed to label the working diluent and wash solution.

D5807

TEST REPORT

CFR(s): 493.1291(d)

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.

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 provide documentation for the source of the Reference Intervals (RI) used for Testosterone tests on the Tosoh AIA 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 6/29/23 at 12:45 pm that there was no documentation for the source of the RI used for Testosterone tests on the Tosoh AIA 900 analyzer. Note: This was previously cited on 7/20/17 and on 10/14/21