Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0710715	01/10/2020
Name of Provider or Supplier	**Street Address, City, State**	
Spectracell Laboratories Inc	6030 North Course Dr, Houston, TX	

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
D0000	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory College of American Pathologists (CAP) proficiency testing records, lab records, and confirmed in interview, the laboratory failed to verify twice annually the accuracy of 4 of 22 analytes on the Siemens XPi 2000 chemistry analyzer for the year 2018 and 2019. (thyroglobulin, thyroxine-binding globulin, Anti-thyroid peroxidase (TPO) antibodies, anti-thyroglobulin antibody) Findings were: 1. Review of the 2018 and 2019 CAP proficiency testing records revealed no documentation of testing for 4 of 22 analytes performed on the XPi 2000 chemistry analyzer. thyroglobulin thyroxine-binding globulin Anti-thyroid peroxidase (TPO) antibodies anti-thyroglobulin antibody 2. Review of the laboratory records revealed no documentation of verifying twice annually the accuracy of the above analytes for the year 2018 and 2019. 3. Further review of the laboratory records revealed the laboratory performed 44544 endocrinology testing annually. 4. An interview with the laboratory QA/QC Director on 1/10/2020 at 1335 hours in the conference room confirmed the above findings. He was unaware the above analytes were not included in their CAP surveys.

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 review of the laboratory verification records and confirmed in interview, the laboratory failed to document complete verification studies for the Siemens XPi 2000 chemistry analyzer. (precision) Findings were: 1. Review of the new Siemens XPi 2000 analyzer (SNJ4122) installed in 06/10/2019 revealed no documentation of the precision studies. 2. An interview with the QA/QC director on 1/13/2020 at 1055 hours confirmed the above findings. He acknowledged that precision should have been assessed.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a review of the laboratory's maintenance records for the Beckman Coulter AU680 chemistry analyzer from March 2018 - December 2019, and staff interview it was revealed the laboratory failed to have documentation of performing all required monthly, quarterly, and every 6 month maintenance. Findings include: 1. A review of the laboratory's maintenance records for the Beckman Coulter AU680 chemistry analyzer from March 2018- December 2019 revealed the following maintenance was required to be performed: a) Monthly Maintenance: - Clean the sample probe, reagent probe, and HbA1c wash wells - Clean the mix bar wash wells - Clean the wash nozzle unit and check the tube mounting joints - Clean the DI water tank, DI filter, and sample probe - Sonicate the sample probe b) Quarterly Maintenance: - Clean Air Filters - Inspect and if needed, replace the DI water filter and sample probe filter - Replace the wash solution roller pump tubing c) Every 6 months Maintenance: - Replace the photometer lamp - Clean the cuvettes and the cuvette wheel 2. Further review of the laboratory's maintenance records for the Beckman Coulter AU680 chemistry analyzer from March 2018- December 2019 revealed the laboratory failed to have documentation of performing the following maintenances: a) Monthly Maintenance was not performed for the following months: - June 2018 - August 2018 - August 2019 - October 2019 b) Quarterly Maintenance was not performed for the following quarters: - 2nd Quarter of 2018 (April- June 2018) - 3rd Quarter of 2018 (July- September 2018) was missing - Clean air filters - Inspect and if needed, replace the DI waster filter and sample probe filter - 1st Quarter of 2019 (January- March 2019) - 2nd Quarter of 2019 (April- June 2019) - 3rd Quarter of 2019 (July- September 2019) - 4th Quarter of 2019 (October- December 2019) c) Every 6 month

	Maintenance was not performed for the following time frames: - Replace Photometer Lamp was done March 4, 2018 and March 28, 2019 - missing the Every 6 month maintenance due September 2018 and September 2019 - Clean the Cuvettes and the Cuvette wheel was done March 26, 2018 -missing the Every 6 month maintenance due September 2018, March 2019, September 2019 3. The laboratory was asked to provide documentation of performing the required maintenance. No documentation was provided. 4. An interview with technical supervisor #1 (as indicated on the CMS 209 form, signed by the laboratory director on 1/5/20) on 1/10/20 at 2:35 p.m. in the office, after review of the records, confirmed the above findings.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) 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. This STANDARD is not met as evidenced by: A. Based on review of the laboratory records and confirmed in interview, the laboratory failed to document calibration verfication for 8 of 24 analytes on the Simenes Immulite 2000 XPi chemistry analyzer. Findings were: 1. Review of the laboratory records revealed the laboratory has 2 Siemens Immulite 2000 XPi chemistry analyzers (System ID F1645, J4122) that both perform the following 24 analytes: C-Peptide Total Testosterone Free Testosterone DHEA-S FSH LH Estradiol Estriol Progesterone SHBG Prolactin Androstenedione IGF Total PSA Free T3 Free T4 Total T4 TSH Anti-thyroglobulin Antibody Anti-TPO Antibody Thyroxine Binding Globulin Thyroglobulin Cortisol Insulin 2. Review of the laboratory calibration records revealed the following 8 of 24 analytes used 2 or less calibrators. Insulin Estriol anti-thyroid peroxidase (anti-TPO) Anti-TG Ab (Anti-Thyroglobulin Ab) IGF SHBG thyroxine-binding globulin (TBG) Thyroglobulin 2. Review of the laboratory quality control records revealed the above analytes are tested with 2 levels of controls twice daily. 3. Review of the laboratory records revealed the laboratory performed 1 calibration verfication for the above analytes once in 2018 for the Siemens analyzer F1645. No documentation of the second calibration verification for 2018 were available for review. 4. Review of the laboratory records revealed the laboratory performed 1 calibration verfication for the above analytes once in 2019 for

	the Siemens analyzer F1645 and one for the Siemens analyzer J4122. No documentation of the second calibration verification for 2019 for either instrument were available for review. 5. An interview with the QA/QC director on 1/13/2020 at 1130 hours in the conference room confirmed the above findings. 41687 B. Based on a review of the laboratory's calibration verification records from 2019 and staff interview, it was revealed the laboratory failed to have documentation of evaluating the calibration verification records for analytes run on the Beckman Coulter AU680 chemistry instrument. Findings include: 1. A review of the laboratory's calibration verification records from 10/3/2019 revealed the following analytes were tested on the Beckman Coulter AU680 chemistry analyzer: - ALB (Albumin) - HDL (High-density Lipoprotein) - LDL (Low-density Lipoprotein) 2. Further review of the records revealed the laboratory failed to have documentation of evaluating the results to determine if the assay was linear for each of the analytes tested. 3. The laboratory was asked to provide documentation of evaluating the results to determine the linearity of the assays. No documentation was provided. 4. An interview with technical supervisor #1 (as indicated on the CMS 209 form, signed by the laboratory director on 1/5/20) on 1/10/20 at 1:40 p.m. in the office, after review of the records, confirmed the above findings.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on review of the laboratory records and confirmed in interview, the laboratory failed to document twice annually the comparison of 23 of 23 it tests on 2 of 2 Siemens Immulite 2000 XPi chemistry analyzer; and 1 of 1 test it tests on the 2 Siemens Immulite 2000 XPi and AU 640 chemistry analyzers. Findings were: 1. Review of the laboratory records revealed the laboratory has 2 Siemens Immulite 2000 XPi chemistry analyzers (System ID F1645, J4122) that both perform the following 23 analytes: C-Peptide Total Testosterone Free Testosterone DHEA-S FSH LH Estradiol Estriol Progesterone SHBG Prolactin Androstenedione IGF Total PSA Free T3 Free T4 Total T4 TSH Anti-thyroglobulin Antibody Anti-TPO Antibody Thyroxine Binding Globulin Thyroglobulin Cortisol 2. . Review of the laboratory records revealed the laboratory has 2 Siemens Immulite 2000 XPi chemistry analyzers (System ID F1645, J4122) and 1 Beckman AU 680 chemistry analyzers that perform the Insulin on all three analyzers. 3. Review of the laboratory records from 2018 - 2019 revealed no comparison of tests among the above instruments of the tests listed above. 4. An interview with the QA/QC director on 1/13/20 at 1100 hours in the conference room confirmed the above findings.