Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2037055	08/31/2021
Name of Provider or Supplier	**Street Address, City, State**	
Sleep And Wellness Medical Associates	31 E Darrah Lane, Lawrenceville, 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
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). 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 verify the accuracy of chemistry and endocrinology test results obtained from the American Proficiency Institute (API) from January 2020 to the date of survey. The findings include: 1. The laboratory received a score of 100 but results were not graded. 2. There was no documented evidence the laboratory verified: a) Estriol events 1,2,3 2020 and 1, 2021. b) Apolipoprotien A1 event 2, 2020. 3. The LD confirmed on 8-31-21 at 2:10 pm accuracy of the PT results were not verified
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 the Quality Control (QC) material and interview with the Laboratory Director (LD), the laboratory failed to put open and expiration dates on Routine Chemistry and Endocrinology QC material in use at the time of survey. The findings include. 1. The expiration date of control material shortens once opened. 2. The laboratory did not put open and expiration dates on: a. Liquichek Immunoassay Plus Control (Lot 85261, 62) b. Lyphochek Liquid Assayed Multiqual Control (Lot 45831, 32 & 33) c. Quantimetrix Vitamin D (Lot 29151 & 52) d. Sex Hormone Binding Globulin (SHBG) Access QC 1 and QC 2 (Lot 9M0076) e. Liquichek Specialty Immunoassy Control Lot (64931 & 33) f. Liquicheck Elevated CRP control lot (35463 & 65461) 3. The LD confirmed on 8/31/21 at 2:30 pm the laboratory failed to put open and expiration dates on the control material. Note: This deficiency was previously cited. The POC state "all current reagents, calibrators, and Quality Controls are labeled with the following: date received, opened and initials"
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. 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 LD failed to ensure that chemistry and endocrinology results performed with the American Proficiency Institute (API) were reviewed and evaluated by the appropriate staff. The findings include: 1. There was no documented evidence the laboratory reviewed: a) Estriol events 1,2,3 2020 and 1, 2021. b) Apolipoprotien A1 event 2, 2020. 2. The LD confirmed on 8/31/21 at 1:50 pm that the LD did not ensure all PT reports were reviewed.