Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2037055	03/30/2023
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
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 surveyor review of Proficiency Testing (PT) records, and interview with the Testing Personnel (TP), the laboratory failed to verify the accuracy and reliability of allergen testing twice a year from January 2022 to the date of survey. The finding includes: 1. The laboratory participated in American Proficiency Institute (API) PT Module Immunology/Immunohematology three events in 2022 that did not cover all 61 allergen analytes performed on the Optigen AP3600. 2. The TP confirmed on 3/30 /23 at 1:30 pm that the laboratory did not verify the accuracy of allergen testing twice a year.
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: a) Based on surveyor observation of Quality Control (QC) material in use, review of the Liquid Assayed Multiqual Control Kit Manufacture Package Insert (MPI) and interview with the Testing Personnel (TP), the laboratory failed to put correct

	expiration dates on QC material for Routine Chemistry tests at the time of survey. The findings include: 1. The expiration date of the QC material shortens once opened. 2. The laboratory had an open date of 3/29/23 and expiration date of 4/12/23 (fourteen days of stability) on QC material in use. 3. The MPI states Bilirubin, Cholesterol, Creatine Kinase, phosphorus and triglycerides have 7 days stability 4. The TP confirmed on 3/30/23 at 11:45 am the laboratory failed to put correct expiration dates on the control material. b) Based on surveyor observation of QC material in use, review of the Liquicxhek Immunoassay Plus Control Kit MPI and interview with the TP, the laboratory failed to put correct expiration dates on QC material for the routine chemistry and endocrinology tests at the time of survey. The findings include: 1. The expiration date of the QC material shortens once opened. 2. The laboratory had an open date of 3/29/23 and expiration date of 4/12/23 (fourteen days of stability) on QC material in use. 3. The MPI states Folate had 4 days stability. 4. The MPI states Estradoil has 8 days stability 5. The TP confirmed on 3/30/23 at 11:45 am the laboratory failed to put correct expiration dates on the control material.
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: Based on surveyor observation of Beckman Coulter CRP Latex calibrator Normal (N) set boxes and interview with the Testing Personnel (TP), the laboratory failed to discard expired Calibrator boxes from 2/1/23 to the date of survey. The finding include: 1. Two boxes of Beckman Coulter CRP Latex calibrator Normal (N) set lot #1066A expired 2/1/23 2. The TP confirmed on 3/30/23 at 12:30 pm that the laboratory failed to discard expired Calibrator.
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 Quality Control (QC) records and interview with the Testing Personnel (TP), the laboratory failed to verify commercial QC material with each new lot and/or shipment of QC used for Allergy tests performed on Optigen

	AP36000 analyzer on the date of survey. The finding includes: 1. There was no documented evidence that QC was verified before being put into use. 2. The TP confirmed on 3/30/23 at 11:20 am that the QC material was not verified before putting in use.
D5805	TEST REPORT CFR(s): 493.1291(c) 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. This STANDARD is not met as evidenced by: Based on surveyor review of the Final Report (FR) and interview with the Testing Personnel (TP) the laboratory failed to ensure that the FR included all the required information on the date of survey. The finding include: 1. A review of ten FR revealed that the Es-triol did not have a normal patient range on the FR. 2. The TP confirmed on 3/30/23 at 10:45 am that FR did not have all the required information.