Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2037055	(X3) Date Survey Completed 06/21/2018
Name of Provider or Supplier Sleep And Wellness Medical Associates	**Street Address, City, State** 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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) 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. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), Quality Control (QC) records and interview with the Technical Consultant (TC), the laboratory failed to follow the QC new lot verification procedure to ensure QC was within the acceptable ranges before it was put into use for analytes performed on the Beckman Coulter AU 480 and Access 2 analyzer from 5/17/16 to the date of the survey. The findings include: 1. The PM stated that QC new lot verification will be performed three times before using. 2. A review of the QC records revealed Liquid Assayed Multiqual Control (Lot 45781, 82, 83), Liquichek C-Reactive Protein (CRP) Control (Lot 35421 & 23) and Sex Hormone Binding Globulin (SHBG) Access QC 1 and QC 2 (Lot 7M0054) were not verified before use. 3. Quantimetrix Vitamin D Control (Lot 29131 & 32) was not run three times prior to using. 4. The TC confirmed on 6/21/18 at 10:30 am that the laboratory did not follow the PM.
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 Technical Consultant (TC), 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 40951, 52 & 53) b. Lyphochek Liquid Assayed Multiqual Control (Lot 45781, 82 & 83) c. Quantimetrix Vitamin D (Lot 29131 & 32) d. Sex Hormone Binding Globulin (SHBG) Access QC 1 and QC 2 (Lot 7M0054) e. Liquichek C-Reactive Protein (CRP) Lot (35421 & 23) 3. The TC confirmed on 6/21 /18 at 11:30 am the laboratory failed to put open and expiration dates on the control material.