Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D2164551	07/08/2025
Name of Provider or Supplier	**Street Address, City, State**	
New Solutions Pain Management Clinics Llc	236 Boston Post Road, Unit 1a, Orange, CT	

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) 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 record review and staff interview, the laboratory failed to follow their established policies and procedure for instrument relocation and sample comparison in the subspecialty of toxicology. Findings include: 1. Record review on 07/08/2025 of the laboratory's 'Instrument Relocation Sample Comparison' validation study for the 'ImmTox 270 Benchtop Analyzer' revealed the following samples with result comparison and acceptance criteria discrepancy: a. Pre instrument relocation: i. Sample ID: CAP 15 1. Results: benzodiazepine (positive), cocaine (negative), opiate (negative), oxycodone (negative) and tramadol (negative). b. Post instrument relocation: i. Sample ID: CAP 15 1. Results: benzodiazepine (positive), cocaine (negative), opiate (positive), oxycodone (negative) and tramadol (positive). c. 'Acceptance Criteria: a minimum of 95% of the lab comparisons for each analyte tested should have 100% concordance'. d. 'Results: the clinical comparison study exhibited 100% concordance across all samples and all analytes'. 2. Staff interview on 07/08/2025 at 10:30 AM with the laboratory's technical consultant (TC) confirmed the above findings. The TC further commented that he/she might suspect sample swapping that resulted in the above discrepancy listed in 1(a) and (b). 3. The laboratory performs approximately 2,600 drug screening tests annually in the subspecialty of toxicology.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)

	(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, record review and staff interview, the laboratory failed to use in date chemical consumables for the 'ImmTox 270 Benchtop Analyzer' in the subspecialty of toxicology. Findings include: 1. Surveyor observation on 07/08 /2025 at 9:15 AM of the laboratory work bench area revealed 2 of 2 'Acid Washing Solution' bottles with a lot number of 230512 and a receive date of 08/28/2024 that are in use and had exceeded the expiration date of 11/2024. 2. Record review on 07/08 /2025 of the laboratory's 'Reagent Handling' standard operating procedure revealed 'Expired reagents are not to be used in patient testing and each lab section is required to regularly review inventories to locate and discard expired reagents'. 3. Staff interview on 07/08/2025 at 9:20 AM with the laboratory's technical consultant confirmed the above findings. 4. The laboratory performs approximately 2,600 drug screening tests annually in the subspecialty of toxicology.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on surveyor observation, record review and staff interview, the laboratory failed to document corrective action when the humidity was outside of the acceptable established range in the subspecialty of toxicology. Findings include: 1. Surveyor observation on 07/08/2025 at 9:25 AM of the laboratory work bench area revealed 1 of 1 digital hygrometer with a serial number of 221950773 and a calibration due date of 12/12/2024 is in use. 2. Record review on 07/08/2025 of the 'Laboratory Temperature and Humidity Log' for the 'ImmTox 270 Benchtop Analyzer' for the period of January 2024 through July 2025 revealed the following: a. Acceptable humidity range is 35 - 80%. b. Lack of documentation of corrective action for 83 of 205 days when the humidity range was below the minimum cutoff of 35%. 3. Record review on 07/08/2025 of the laboratory's 'Environmental Conditions - Control & Monitoring' standard operating procedure revealed the following: a. 'Record the temperature and humidity on the Room Temperature and Humidity Log'. b. 'If any data is determined to be invalid, the incident must be documented by completing an instrument corrective action report'. 4. Staff interview on 07/08/2025 at 11:45 a.m. with the laboratory's technical consultant confirmed the above findings. 5. The laboratory performs approximately 2,600 drug screening tests annually in the subspecialty of toxicology.