Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D2014059	10/01/2018
Name of Provider or Supplier	**Street Address, City, State**	
Island Pain Specialist Pc	1111 Broadhollow Road, Suite 114, Farmingdale, NY	

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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on a surveyor's review of the laboratory's procedure manual and an interview and confirmed with the laboratory director, the laboratory failed to have a procedure manual that is comprehensive. FINDINGS: The procedure manual did not include: 1. A written procedure describing laboratory's batch testing system for toxicology testing which are collected daily but tested three times per week; 2. A written procedure

	describing the laboratory's turnaround time for toxicology testing from sample collection to processing and to when final results are entered into the lab computer system; 3. A written procedure describing laboratory's criteria for QC acceptability.
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, Levey Jennings records and interview with the laboratory director, the laboratory failed to establish and verify the criteria for acceptability of all control materials in calendar year 2017 and up to survey date. FINDINGS: On 10/1/2018 at approximately 11:30 AM, the laboratory director confirmed the surveyor's review of QC records finding that the laboratory failed to establish criteria for QC acceptability for toxicology analytes tested on the Agilent 6420 Triple Quad LC/MS System analyzer and failed to evaluate and document shifts in QC results.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on a surveyor review of the laboratory's records and confirmed during an interview with the laboratory director at the time of survey at approximately 11:30 AM, the laboratory director failed to ensure that the laboratory's quality assessment (QA) program was followed and the QA reviews were performed in calendar year 2017 and up to August 2018. Refer to D5403, D5469