Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D1084138	08/11/2021
Name of Provider or Supplier	**Street Address, City, State**	
Johnston Pain Management, Pa	250 Huff Dr, Jacksonville, NC	

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 review of laboratory procedure manual and interview with laboratory director (LD) 8/11/21, the procedure manual failed to include the laboratory's system for entering results in the patient record. Findings: Review of laboratory procedure manual revealed no procedure for the laboratory's system of entering results in the patient record. Interview with LD at approximately 12:38 p.m. confirmed the procedure manual failed to include the laboratory's system for entering results in the patient record.

D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on review of laboratory procedures, review of laboratory validation records for the AB Sciex 4500 LCMS toxicology analyzer and interview with testing personnel (TP#1) and LD 8/11/21 the laboratory failed to perform a specimen stability study that met the specimen storage criteria performed by the laboratory. Findings: Review of laboratory procedure "Quantitative Determination of Drugs and Metabolites in Urine via LCMS" states "Specimen Acceptability...reject samples for any of the following reasons...sample collected more than 30 days prior and/or not refrigerated." Review of laboratory validation records revealed "Validation summary for director review - Quantitative protocol...Five samples for each of three concentrations were left out for a total of 5 days at room temperature." The validation records included the stability study for specimens kept at room temperature for 5 days but failed to include a stability study for specimens stored in a refrigerator. During interview at approximately 11:30 a.m. TP #1 stated most samples were run within 3 days, but could be run up to 30 days after collection if stored in the refrigerator. She also stated samples that were not tested upon receipt in the laboratory were stored in the refrigerator until testing was performed. Interview with LD at approximately 12:12 p. m. confirmed specimens can be stored for up to 30 days in the refrigerator before being tested. She also confirmed the laboratory did not perform a stability study that included refrigerated specimens.