

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D1053599	(X3) Date Survey Completed 02/05/2019
Name of Provider or Supplier Pain Treatment Associates, Llc	Street Address, City, State 1410 Doctors Drive, West Plains, MO	
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	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of procedures, quality control (QC) and interview with technical supervisor #2 the laboratory failed to provide an approved written procedure for establishing acceptable QC limits for seven of fourteen urine toxicology analytes. Findings: 1. Review of urine toxicology procedure shows no acceptable QC limits provided. 2. Review of amphetamine, cocaine, oxycodone, PCP, barbiturates, buprenorphine and opiates QC showed laboratory establishing a 10% range for one</p>

standard deviation. 3. Interview with the technical supervisor on February 5, 2019 at 1:00 PM confirmed the laboratory failed to provide an approved written procedure for establishing acceptable QC limits for seven toxicology analytes.