

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  34D2054245	<b>(X3) Date Survey Completed</b>  12/15/2021
<b>Name of Provider or Supplier</b>  Preferred Pain Management & Spine Care, Pa	<b>Street Address, City, State</b>  1100 Revolution Mill Drive, Suite 1, Section B, Greensboro, NC	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5403</b>	<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 laboratory procedures and interview with general supervisor (GS) 12/15/21, the laboratory procedures for Urine Creatinine (UCREA), Amphetamines (AMPH), Buprenorphine (BUP) and Oxycodone (OXY) were not complete for the testing performed. Findings: 1. The laboratory procedure for UCREA failed to include the type and level of quality control (QC) material used. Review of laboratory procedure "IR500 Urine Creatinine Validity Test" revealed "Material Required: Reagent, Controls, Calibrators...Controls...Cat #GPR560SC.". The procedure included</p>

a catalog number and failed to include the type and level of QC material used. Exit interview with GS at approximately 2:30 p.m. confirmed the UCREA procedure was not complete. 2. The laboratory procedure for AMPH failed to include the specific cut-off value, failed to include the specific levels and values of QC material used and failed to include the specific values of calibrator used. a. Review of laboratory procedure "IR500 Amphetamines Enzyme Immunoassay" revealed "Intended Use: The Lin-Zen International, Inc. (LZI) Amphetamines 500 Enzyme Immunoassay (cutoff value of 500 ng/mL) and Amphetamines Enzyme Immunoassay (cutoff value of 1000 ng/mL) are intended for the qualitative and semi-quantitative determination of methamphetamine...". The procedure failed to specify the cut-off value in use by the laboratory. b. Review of laboratory procedure "IR500 Amphetamines Enzyme Immunoassay" revealed "Material Required: Reagent, Controls, Calibrators II. Amphetamines 500: Synermed Multi QC Material...Level 1 - 375 ng/mL...Level 2 - 625 ng/mL...III. Amphetamines 1000:...Lin-Zhi Amphetamines QC Material, Level 1 - 750 ng/mL...Level 2 - 1250 ng/mL...". The procedure failed to specify the QC used by the laboratory. c. Review of laboratory procedure "IR500 Amphetamines Enzyme Immunoassay" revealed "Material Required: Reagent, Controls, Calibrators II. Amphetamines 500: Synermed Multi Calibrators-Amphetamines 500 ng/mL...Level #1: negative...Level #2:...250 ng/mL...Level #3:...500 ng/mL...Level #4...750 ng/mL...Level #5...1000 ng/mL...III. Amphetamines 1000...Lin-Zhi Amphetamines Calibrators -Amphetamines 1000 ng/mL...Level #1: negative...Level #2:...250 ng/mL...Level #3:...500 ng/mL...Level #4...750 ng/mL...Level #5...1000 ng/mL...". The procedure failed to specify the calibrators used by the laboratory. 3. The laboratory procedure for BUP failed to include the specific cut-off value and failed to include the levels and values of quality control (QC) material used. a. Review of laboratory procedure "IR500 Buprenorphine Enzyme Immunoassay" revealed "Intended Use: The Lin-Zhi International (LZI) Buprenorphine Enzyme Immunoassay is intended for the qualitative and semi-qualitative determination of norbuprenorphine (buprenorphine metabolite) in human urine at a cutoff value of 5 and 10 ng/mL...". The procedure failed to specify the cut-off value in use by the laboratory. b. Review of laboratory procedure "IR500 Buprenorphine Enzyme Immunoassay" revealed "Material Required: Reagent, Controls, Calibrators...LZI Single QC Material, Buprenorphine LZ0272, LZ0274...". The procedure included the part numbers of the QC reagents and failed to include the levels and values of QC material used. Interview with GS at approximately 3:00 p.m. confirmed the BUP procedure was not complete and current. 4. The laboratory procedure for OXY failed to include the specific cut-off value used for the assay, failed to include the specific levels and values of quality control (QC) material used and failed to include the specific value of the level 3 calibrator used. a. Review of laboratory procedure "IR500 Oxycodone Enzyme Immunoassay" revealed "Intended Use: The Lin-Zhi International, Inc. (LZI) Oxycodone Enzyme Immunoassay is intended for the qualitative and semi-quantitative determination of oxycodone and its metabolite, oxymorphone, in human urine, at cutoff values of 100 ng/mL or 300 ng/mL...". The procedure failed to specify the cut-off value used by the laboratory. b. Review of laboratory procedure "IR500 Oxycodone Enzyme Immunoassay" revealed "Material Required: Reagent, Controls, Calibrators...LZI Single QC Material: Oxycodone 100 ng/mL Cutoff: Level 1 - Contains 75 ng/mL oxycodone, Level 2 - Contains 125 ng/mL oxycodone...Oxycodone 300 ng/mL Cutoff: Level 1 - Contains 225 ng/mL oxycodone, Level 2 - Contains 375 ng/mL oxycodone...". The procedure failed to specify the QC used by the laboratory. c. Review of laboratory procedure "IR500 Oxycodone Enzyme Immunoassay" revealed "Material Required: Reagent, Controls, Calibrators...LZI Single Calibrator Material, Levels 1-5...Level #3: Cutoff Calibrator 1 or 2 - 100 or 300 ng/mL oxycodone...". The procedure failed to specify the Level #3 calibrator used by the laboratory. Interview

with GS at approximately 3:00 p.m. confirmed the OXY procedure was not complete and current.