Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D2165790	12/15/2021
Name of Provider or Supplier	**Street Address, City, State**	
Progressive Pain Partners, Pllc	2508 N Queen Street, Kinston, 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 procedures and interview with general supervisor (GS) 12/15/21, the laboratory procedures for Buprenorphine (BUP) and Oxycodone (OXY) were not complete and current for the testing performed. Findings: 1. 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 used 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 material and failed to include the levels and values of QC material used. Interview with GS at approximately 3:15 p.m. confirmed the BUP procedure was not complete and current. 2. 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 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 3:15 p.m. confirmed the OXY procedure was not complete and current.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with GS 12/14/21, the laboratory failed to validate the performance specifications for the testing performed on the IR-500 analyzer before beginning patient testing in May of 2019. Review of laboratory record "(current laboratory name) Validation Letter IR-500 - Shared Equipment" revealed "Validation data performed May 2016 on the Synermed IR-500 serial #130210 under the laboratory (previous laboratory name) has been reviewed and approved by the (current laboratory name) Laboratory Director.. This instrument is approved to also run clinical testing for (current laboratory name) effective 5/21/19.". The validation of performance specifications performed by a previous laboratory failed to meet the validation of performance specifications for the testing performed on the IR-500 analyzer. Interview with GS at approximately 11:00 a.m. confirmed the current laboratory failed to validate the performance specifications for the testing

	performed on the IR-500. She stated they were told that they could just use the data obtained from the previous laboratory's validation.
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 records and interview with GS 12/14/21, the laboratory failed to validate the performance specifications for the Ethyl Alcohol testing performed on the IR-500 analyzer and all toxicology testing performed on the LCMS analyzer before patient testing began in May of 2019. Findings: 1. The laboratory failed to validate the performance specifications for the Ethyl Alcohol testing performed on the IR-500 analyzer. Review of laboratory record "(current laboratory name) Validation Letter IR-500 - Shared Equipment" revealed "Validation data performed May 2016 on the Synermed IR-500 serial #130210 under the laboratory (previous laboratory name) has been reviewed and approved by the (current laboratory name) Laboratory Director. This instrument is approved to also run clinical testing for (current laboratory name) effective 5/21/19.". The validation of performance specifications performed by a previous laboratory failed to meet the validation of performance specifications for Ethyl Alcohol testing performed on the IR-500 analyzer. Interview with GS at approximately 11:00 a..m. confirmed the laboratory failed to validate the performance specifications for the Ethyl Alcohol testing performed on the IR-500. She stated they were told that they could just use the data obtained from the previous laboratory's validation. 2. The laboratory failed to validate the performance specifications for all toxicology testing performed on the LCMS analyzer. Review of laboratory record "(current laboratory name) Validation Letter LCMS - Shared Equipment" revealed "Validation data performed September 2018, under the name of (previous laboratory name) on the Schimadzu LC MS 8040 series tandem mass spectrometer serial #010945350027US,...has been reviewed and approved by the (current laboratory name) Lab Director. This instrument is approved for clinical testing by (current laboratory name) effective 5/21/19.". The validation of performance specifications performed by a previous laboratory failed to meet the validation of all toxicology testing performed on the LCMS analyzer. Interview with GS at approximately 11:00 a..m. confirmed the laboratory failed to validate the performance specifications for all toxicology testing performed on the LCMS analyzer. She stated they were told that they could just use the data obtained from the previous laboratory's validation.