Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D2144824	(X3) Date Survey Completed 12/15/2021
Name of Provider or Supplier Bellamy Pain Management	**Street Address, City, State** 1050 Revolution Mill Drive, Studio 7a, Greensboro, 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) 12/13/21, the laboratory procedure for Oxycodone (OXY) failed to include the specific cut-off value used for the assay, the specific levels and values of quality control (QC) material used and the specific value of the level 3 calibrator used. Findings: 1. 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. 2. 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. 3. 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.
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 when the instrument was relocated in September of 2020. Findings: Review of laboratory record "MEMO TO FILE" revealed "On September 1, 2020, (current laboratory name) laboratory moved location to a larger room next door... Major equipment, the LCMS and IR-500, remained the same and were moved a short distance manually on a rolling table. Per (company name) Standard Operating Procedures, QC verification was performed on both instruments after the move and before patient samples were run. Both QC verifications passed successfully. IR-500 data can be found under the lab name (name of laboratory sharing instrument); this business occupies the same space and instruments as (laboratory name), but on different days." The QC verification data failed to meet all performance specifications required when an instrument is moved from one location to another. In addition, the IR-500 data performed by another laboratory sharing the same instrument failed to meet the validation of performance specifications for the testing performed on the IR-500 analyzer. Interview with GS at approximately 3:40 p.m. confirmed the current laboratory failed to validate the performance specifications for the testing performed on the IR-500. She stated they did not realize they would have to do a complete validation of the performance specifications if an analyzer was only moved a short distance. She also stated they did not realize they could not use the data obtained by another laboratory even if the analyzer was shared.
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 testing performed on the LCMS analyzer when the instrument was relocated in September of 2020. Findings: Review of laboratory record "MEMO TO FILE" revealed "On September 1, 2020, (laboratory name) laboratory moved location to a larger room next door...Major equipment, the LCMS and IR-500, remained the same and were moved a short distance manually on a rolling table. Per (company name) Standard Operating Procedures, QC verification was performed on both instruments after the move and before patient samples were run. Both QC verifications passed successfully. IR-500 data can be found under the lab name (name of laboratory sharing instrument); this business occupies the same space and instruments as (laboratory name), but on different days." The QC verification data failed to meet all performance specifications required when an instrument is moved from one location to another. Interview with GS at approximately 3:40 p.m. confirmed the current laboratory failed to validate all performance specifications for the testing performed on the LCMS analyzer. She stated they did not realize they would have to do a complete validation of the performance specifications if an analyzer was only moved a short distance.