Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D2157354	12/15/2021
Name of Provider or Supplier	**Street Address, City, State**	
Emergeortho, Pa	1050 Revolution Mill Drive, Suite 1a And 1b, 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 the compliance consultant and testing personnel (TP #1) 12/15/21, the laboratory procedures for Buprenorphine (BUP), Oxycodone (OXY), and Ethyl Glucuronide (EtG) were not complete 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-quantitative 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: Reagents, 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. 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 quality control (QC) reagent 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: Reagents, 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. Cat # LZ0245b, LZ0247b ..." 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. 3. The laboratory procedure for EtG failed to include the specific cut-off value and failed to include the levels and values of quality control (QC) and calibration material used. a. Review of laboratory procedure "IR500 Immunalysis Ethyl Glucuronide Immunoassay" revealed "Intended Use: The Immunalysis Ethyl Glucuronide (EtG) Urine HEIA is a homogenous enzyme immunoassay with cutoffs of 500 ng/mL and 1000 ng/mL. ..." The procedure failed to specify the cut-off value used by the laboratory. b. Review of laboratory procedure "IR500 Immunalysis Ethyl Glucuronide Immunoassay" revealed "Material Required: Reagent, Controls, Calibrators ... Controls: Cat # C341UR-5-2-500 Calibrators: Cat # NEG-10-1, 10031-5, C341 UR-5-1-500, C341 UR-5-1-1000, 10034-5 ...". The procedure included the part numbers of the QC and calibration material and failed to include the levels and values of the QC and calibration material used. Interview with the compliance consultant and TP #1 at approximately 3:00 p.m. confirmed the BUP, OXY, and EtG procedures were not complete and current.