Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D2139757	05/01/2018
Name of Provider or Supplier	**Street Address, City, State**	
John D Zipperer Jr Md Llc	170 Northpointe Parkway, Suite 500a, Amherst, NY	

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
D3009	FACILITIES CFR(s): 493.1101(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements. This STANDARD is not met as evidenced by: Based on a review of a reference laboratory tracking form and an interview with the manager/supervisor and the testing person, the laboratory is referring toxicology confirmation tests to a laboratory that does not hold a CLEP laboratory permit. Findings: 1. Patient specimens sent to a NY laboratory from an out of state laboratory are considered NY specimens and fall under all NY regulations. NY requires all specimens referred from a NY laboratory to another laboratory to be certified by the Clinical Laboratory Evaluation Program (CLEP). 2. At approximately 10:00 AM it was confirmed by laboratory staff that specimens requiring toxicology confirmation were sent to Acculab LLC, 1043 Perdigo Way, Bowling Green, KY 42103. This laboratory does not have a NY State Clinical Laboratory Permit.
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 a review of the laboratory written procedure manual, package insert for each analyte, a patient report, and an interview with testing person, manager and director, the laboratory reference range for buprenorphine, pH and creatinine do not match in procedure, package insert and patient report with no explanation as to discrepancies. Findings: At approximately 11:30 AM based on a review of laboratory documents and confirmed with laboratory staff the following discrepancies were identified: 1. For Buprenorphine, the written procedure and the patient report indicate a cutoff value of 20 ng/ml while the package insert indicates a value of 5 ng/ml. 2. For pH, the package insert states normal values of 3.0-11.0 units, the written procedure indicates 2.9-11.6 units, and the patient report indicates 3.9-10.1 units. 3. For Creatinine, package insert shows a normal value of 22-250 mg/dl, written procedure 20-200 mg/dl and patient report is 19-200.