Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0676164	01/26/2021
Name of Provider or Supplier	**Street Address, City, State**	
Sw Medical Laboratory, Inc	3151 Airway Ave, Suite M1, Costa Mesa, CA	

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 Surveyor review of laboratory's policy & procedure, random patient sample, quality control (QC) and proficiency testing (PT) records for the years of 2019 and 2020, and interview with the laboratory technical supervisor on January 26, 2021 at 2: 35 pm, the laboratory failed to have a step-by-step performance of the procedure and quality control procedure for the LC-MS method. The findings include: 1. The laboratory uses LC-MS method for the confirmation and measurement of various drugs. During the confirmation and measurement run it uses 2 controls (one of them is below cut-off value) in quadruplicate. However, the laboratory's procedure manual

	did not describe step-by-step procedure for sample preparation. Moreover, it did not indicate the criteria to determine an acceptable control results. 2. The laboratory technical supervisor on January 26, 2021 at 2:35 pm, affirmed that the laboratory procedure manual did not have a step-by-step performance of the procedure and quality control procedure for the LC-MS method. 3. The laboratory's testing declaration form, signed by the laboratory Director on 1/26/2021, stated that the laboratory performs 1,260,000 tests in drug confirmation, annually.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy and procedure, QC & PT records for the years of 2019 and 2020, and interview with the laboratory technical supervisor on January 26, 2021 at 2:35 pm, the laboratory director failed to ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided. The findings include: See D5403.