Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D1091457	11/28/2018
Name of Provider or Supplier	**Street Address, City, State**	
Advanced Pain Medicine	1009 Beaver Grade Road, Moon Township, PA	

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 procedure manuals, Accessioning log, patient saliva drug screen order, and interview with the General Supervisor (GS) #2, at the time of complaint investigation, the laboratory failed to have a procedure manual for the Oral fluid drug screening tests performed. Findings include: 1. Patient accessioning logs (with patient names) were observed on the day investigation (11/28/18). The complainant's accessioning logs reviewed at the time of investigation states" All samples get a 10 panel drug screen unless otherwise noted" 2. The surveyors identified some numbers (#3 next to the complainant's 2nd screening specimen)

	circled on the accessioning log. 3. The GS confirmed when interviewed around on 11 /28/18, that the numbers represented analytes screened for each patient instead of the 10 panel drug screen indicated on the accessioning log 4. The laboratory could not provide any policy for the selection of analytes to perform, when sample volume is low, and is not enough to perform all 10 panel drug screens as indicated. 5. The complainant's Saliva drug screen (1st screening) order reviewed at the time of investigation, revealed 19 saliva drug profiles were ordered for confirmatory testing and a handwritten note - QNS (Quantity not Sufficient) for saliva drug screening. 7. The laboratory did not perform the saliva drug screening but performed confirmatory testing. 8. The laboratory did not have criteria available for performing saliva drug confirmatory testing without performing the drug screening. 9. The GS #2 confirmed the findings above on 11/28/2018 around 1:00 pm.