Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2146684	03/08/2019
Name of Provider or Supplier	**Street Address, City, State**	
Michelle Aszterbaum, Md Inc	360 San Miguel Ste 406, Newport Beach, 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 procedure manual, patient testing records, and interview with the laboratory Director on March 8, 2019 at 11:45 am, the laboratory failed to include into its procedure manual the microscopic examination, including the detection of inadequately prepared slides. The findings include: a. The laboratory performs microscopic examination of skin tissue histology slides which is prepared by Harris Histology lab. However, the laboratory did not have a procedure for the microscopic examination and the detection of inadequately prepared slides. b. On March 8, 2019 at 11:45 am laboratory Director affirmed that it did not have a

	procedure for microscopic examination and the detection of inadequately prepared slides. c. The laboratory testing declaration form, signed by the laboratory Director on March 7, 2019, indicates that the laboratory performs about 400 tests in histopathology, annually.
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory policies and procedures, lack of corrective action policy and procedure, random patient testing records, and interview with the laboratory Director on March 8, 2019 at 12:05 pm, the laboratory failed to establish and follow a corrective action policy and procedure to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. The findings include: a. For the patient slide number AZ18-409, the laboratory's test record shows the specimen source as left superior lateral buccal cheek, but on the tissue slide it is labeled as rsulpatbucc.c. From the record it is clear that the histology lab that makes the slide mislabeled the specimen source as right instead of left. However, the laboratory did not make any corrective action. b. On March 8, 2019 at 12:05 pm laboratory Director affirmed that the histology lab made mistake in labeling the tissue slide, and the testing laboratory did not make any effort to correct the mistake. c. The laboratory testing declaration form, signed by the laboratory Director on March 7, 2019, indicates that the laboratory performs about 400 tests in histopathology, annually.