

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0615441	(X3) Date Survey Completed 12/05/2019
Name of Provider or Supplier Michael J Fazio Md Inc	Street Address, City, State 1525 Response Rd, Sacramento, 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	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy & procedure, 8 random patient test records from 2018-2019, and interview with the Laboratory personnel, the laboratory failed to have and follow step-by-step performance of the procedure for processing biopsy tissues. The findings include: a. The laboratory performed a frozen section histopathology from a shaved biopsy tissue, final size 3.1 cm for the patient # 11983 on 2/19/2019. The histopathology slide showed 3 pieces of tissue sections of various sizes. The laboratory personnel told that the tissue was trisected however; the laboratory did not have any documentation showing that the tissue was trisected into 3</p>

sections. The laboratory did not have documentation showing that it had the step-by-step tissue processing procedure and the laboratory personnel followed the procedure and documented all the steps. b. The laboratory staff, on 12/05/2019 at 12:10 pm, affirmed that the laboratory did not have any step-by-step procedure available to and followed by the laboratory personnel. c. The laboratory's testing declaration form, signed by the laboratory Director on 11/20/2019, stated that the laboratory performs 3,763 tests, 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's policy & procedure, patient test records, histopathology proficiency testing procedure and documents, and interview with the Laboratory personnel, the laboratory failed to take any corrective action when proficiency testing results did not concur with the laboratory's results for the January - June, 2019 PT event. The findings include: a. As part of laboratory's proficiency testing, the laboratory sent out split sample to Path Logic lab. A total of 11 patients samples were sent out for result comparison. The laboratory director reviewed the results on July 15, 2019, and found equivalent diagnosis. However, the testing records showed that out of 11 reports, 2 patients report did not have equivalent result. The result from Path Logic showed patient # 12097 had a diagnosis of BCC but the laboratory's diagnosis was trichoepithelioma; and for patient # unknown, date of biopsy 6/26/19, Path Logic diagnosis was SCC but the laboratory's diagnosis was BSC. The laboratory did not have any corrective action for the above result discrepancy. b. The laboratory staff, on 12/05/2019 at 12:20 pm, affirmed that the laboratory did not take any corrective action for the above PT result discrepancy. c. The laboratory's testing declaration form, signed by the laboratory Director on 11/20/2019, stated that the laboratory performs 3,763 tests, annually.