Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0156337	(X3) Date Survey Completed 08/13/2019
Name of Provider or Supplier Orbuch Brand Dermatology Associates, Llp	**Street Address, City, State** 4277 Hempstead Turnpike, Suite 206, Bethpage, 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
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 the Mohs laboratory's procedure manual and interview with the Mohs histotech and the office manager, the laboratory failed to establish written procedures for acceptance of staining quality of the Hematoxylin & Eosin (H&E) stain on each day of Mohs surgery.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)

	The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a surveyor review of temperature records an and interview with the Mohs histotech and the office manager, the laboratory failed to follow the manufacturer's temperature requirement. Findings Include: It was confirmed by the histotech on August 13, 2019 at approximately 10:30 AM that the laboratory failed to follow the manufacturer's written criteria to monitor and document the temperature of the room and humidity where Moh's testing is performed in calendar year 2018 and up to survey date.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a surveyor review of Quality Control (QC) records and an interview with the Mohs histotech, the laboratory failed to have the Mohs surgeon review and sign the quality control acceptability of the Hematoxlyin and Eosin (H&E) stain used for Mohs surgery slides. Findings include: 1. It was confirmed with the Mohs histotech on August 13, 2019 at approximately 10:30 AM that the laboratory failed to perform and document the acceptability of the Hematoxlyin an Eosin Stains performed in calendar year 2018 and up to survey date. 2. Approximately 200 patient slides were tested and results reported for Mohs surgery during the above dates.