Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	06D1035398	08/31/2018
Name of Provider or Supplier	**Street Address, City, State**	
Bella Derma, Llc	1140 Edwards Village Blvd, Ste B200, Edwards, CO	

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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on a lack of accuracy verification (comparison testing) documentation and staff confirmation, the laboratory failed to twice annually verify the accuracy of potassium hydroxide (KOH) fungal and yeast examinations where no records were provided to show any comparison activity was conducted for this test in 2017 and 2018 and approximately 200 patient specimens are tested annually.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on the review of the quality assessment (QA) plan for the general laboratory systems and staff interview, the laboratory failed to establish written policies and procedures for staff to follow in 2017 and 2018 for an ongoing mechanism to monitor, assess, and take corrective action as needed for the general laboratory systems to include evaluation of personnel competency, complaint investigations, communications and evaluation of proficiency testing performance (accuracy verification). Findings include: a. The staff provided a QA Plan that did not include

	evaluation of personal competeny, complaint investigations, communications and evaluation of proficiency testing performance (accuracy verification). b. The staff confirmed the laboratory had not written policies to evaluate all general quality issues in the laboratory.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the procedure manual and staff interview, the laboratory failed to have available a written procedure for reading Mohs surgery histopathology slides, reviewed and signed by the laboratory director, for staff to follow in 2017 and 2018. Staff stated the laboratory has a written procedure for reading Mohs surgery histopathology slides but they were unaware of where the test procedure could be located.
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 review of the procedure manual and staff interview, the laboratory failed to have complete written procedures in place that contain all required elements for testing personnel to follow for potassium hydroxide (KOH) fungal and yeast examinations in 2017 and 2018. Findings include: a. The procedure for KOH fungal and yeast examinations failed to include requirements for the description of the course of action to take if the test system becomes inoperable and pertinent literature references. b. Staff confirmed that the current test procedure did not contain all applicable elements.