Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2194282	06/21/2021
Name of Provider or Supplier	**Street Address, City, State**	
Dazzling Dermatology, Pllc	22029 Sr 7 Ste 101, Boca Raton, FL	

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
D0000	An initial certification survey conducted at DAZZLING DERMATOLOGY, PLLC on 06/21/2021 found the clinical laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories.
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 record review and interview, the laboratory failed to establish a Quality Assessment (QA) procedure for monitoring, assessing and correcting identified problems from January to June 2021. Findings include: Review of laboratory records revealed that there was no QA procedure. During an interview on 06/21/2021 at 10:00 am, the LD confirmed that the procedure manual did not include a QA policy.
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 record review and interview, the laboratory written' s procedure manual was incomplete. Findings include: Review of the procedure manual signed by the laboratory director (LD) on 6/21/21, did not include a procedure for proficiency testing, quality control and quality assessment. During an interview on 6/21/21 at 10: 00 AM, the LD acknowledged that the procedure manual failed to include the policies listed above.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory director (LD) failed to ensure the laboratory had a quality assurance policy for the laboratory since January 2021 to present. Findings include: Review of the procedure manual revealed that there was no quality assessment policy to monitor, asses and correct problems identified in the pre-analytic, analytic and post-analytic systems. During an interview on 06/21/2021 at 10: 00 am with the LD, he confirmed that he failed to ensure the laboratory had a QA policy.