Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2167996	08/07/2025
Name of Provider or Supplier	**Street Address, City, State**	
Hightower Dermatology	957 E Del Webb Blvd Ste 101, Sun City Center, 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 unannounced CLIA recertification survey was conducted at Hightower Dermatology on 08/07/25. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation, record review, and interview, three of three tissue inks used for Histology patient testing failed to be labeled with identity, preparation and expiration dates. Findings Included: 1. On 08/07/25 at 10:20 a.m., three of three Formalin containers filled with tissue inks used for Histology patient testing failed to be labeled with identity, preparation and expiration dates. 2. The Laboratory Director on 08/07 /25 at 10:20 a.m. confirmed the three of three Formalin containers were filled with tissue inks used for Histology patient testing failed to be labeled with identity, preparation and expiration dates. 3. The Chemical Reagent Logs for 2023, 2024, and 2025 failed to have documentation of lot number, expiration date, and date received for Tissue Ink for 2023, 2024, and 2025. The Laboratory Director on 08/07/25 at 10: 50 a.m. confirmed the laboratory failed to document and monitor the lot number, expiration date, and date received for Tissue Ink.
D6080	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(c)

	(c) The laboratory director must: (c)(1) Be onsite at least once every 6 months, with at least 4 months between the minimum two on-site visits. Laboratory directors may elect to be on-site more frequently and must continue to be accessible to the laboratory to provide telephone or electronic consultation as needed; and (c)(2) Provide documentation of these visits, including evidence of performing activities that are part of the laboratory director responsibilities. This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to establish a policy to reflect the requirement of being onsite once every 6 months to include evidence of performing activities that are part of the Laboratory Director's responsibilities. Findings included: 1. The policy and procedure manual, which had approval dates for each policy and procedure individually, was reviewed. No policy could be found regarding documenting being on site every 6 months to include evidence of performing activities that are part of the Laboratory Director's responsibilities. 2. An interview was conducted with the Office Manager on 08/07/25 at 11:00 a.m. The Office Manager stated the laboratory had not been aware of this requirement.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and 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 failed to establish a comprehensive quality assessment program to encompass all laboratory services for 06 /2023-8/2025. Findings included: 1. The policy and procedure manual, which had approval dates for each policy and procedure individually, was reviewed but failed to include a quality assessment procedure to encompass General, Pre-Analytic, Analytic, and Post-Analytic systems. There was no documentation provided for review at the time of the survey of the Laboratory Director performing quality assessment checks of all the laboratory systems. 2. The Laboratory Director on 08/07/25 at 10:50 a.m. confirmed there was no policy or documents to review of comprehensive quality assessment by the Laboratory Director.