Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2274803	06/03/2025
Name of Provider or Supplier	**Street Address, City, State**	
Leading Edge Dermatology Llc	333 Nw 70 Avenue Unit 116, Plantation, 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 announced CLIA recertification survey was conducted at LEADING EDGE DERMATOLOGY LLC on June 6, 2025. The laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiency:
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. This STANDARD is not met as evidenced by: Based on review of Quality Control (QC) records and staff interview, the Laboratory failed to follow the laboratory policy for review of the control slide stain quality since January of 2024 through May 2025. The findings included: 1-Review of the CMS-209 form submitted on 06-03-2025 and signed by the Laboratory Director (LD) revealed that there are three testing personnel (TP) #1 (the LD), TP#2 and TP#3. 2-Review of the daily QC records showed that the documentation had been signed by the histotechnician for 01/11/2024, 01/25/2024, 02/08/2024, 02/22/2024, 03/07/2024, 03 /21/2024, 04/04/2024, 04/18/2024, 05/02/2024, 05/16/2024, 05/30/2024, 06/05/2024, 06/13/2024, 06/27/2024, 07/11/20234, 08/08/2024, 08/22/2024, 09/05/204, 09/19 /2024, 09/26/2024, , 10/03/204, 10/17/2024, 10/31/2024, 11/12/204, 12/04/2024, 12/12 /2024, 01/09/2025, 01/23/2025, 02/06/2025, 02/20/2025, 03/06/2025, 03/20/2025, 04 /03/2025, 04/17/2025, 05/01/2025, 05/15/2025 and 05/29/2025. 3-Review of the Quality Management procedure, section 4. Monitoring of the Quality Control Testing stated, "In Histopathology ...The Quality Control Process is documented on the Stain Quality Control Log and signed by the Laboratory Director." 4-Review of the policy

	and procedure manual signed and approved by the Laboratory Director did not match the "approved" signature from QC records in item 2. 5-Interview on 06/03/2025 at 12: 10 PM with TP#2, confirmed that the daily QC records approval was not the Laboratory Director's signature.