Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	42D1087626	08/29/2024
Name of Provider or Supplier	**Street Address, City, State**	
Mt Pleasant Dermatology, Llc	570 Long Point Road, Suite 200, Mt Pleasant, SC	

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 onsite announced CLIA recertification survey was conducted on August 29, 2024, at the clinical laboratory of Mt. Pleasant Dermatology, LLC by the South Carolina Department of Public Health's Bureau of Nursing Homes and Medical Services. The laboratory was found to be out of compliance with 42 CFR Part 493, CLIA Requirements for Laboratories. The following is description of Standard Level deficiencies cited:
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 review of laboratory policy and procedure, lack of laboratory documentation, and staff interview, the laboratory failed to follow a written policy and procedure in place for Quality Assessments. Findings included: 1. An onsite survey on August 29, 2024, at 10:00am revealed a policy entitled "Quality Assessment Policy" signed by the laboratory director on August 27, 2024. 2. Review of laboratory records reveals a lack of documentation for the following: a. "Histology competency program through ASDP." b. "Slide review program for pathologist through ASDP." c. "Outside consultation comparison" 3. Review of quality assessment records reveals a lack of documentation of biannual peer reviews for tissue diagnosis. 4. In an interview with the Technical Consultant on August 29, 2024, at 2:30pm in the laboratory, the findings were confirmed.
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. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on laboratory documentation and staff interview, the laboratory failed to document reaction of control slides for each special stain. Findings included: 1. Review laboratory procedures reveal a lack of quality control protocol for each special stain. 2. Review of laboratory documentation reveals a lack documentation for control slide reactions for special stains. 3. In an interview with the Technical Consultant (TC) on August 29, 2024, at 2:30pm in the laboratory, the TC indicated that each special stain has a control slide peformed with to confirm resuilts: however, the documentation of the reaction of control slides was not recorded.