Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1057816	(X3) Date Survey Completed 03/04/2021
Name of Provider or Supplier Advanced Dermasurgery Associates	Street Address, City, State 12222 Coit Road, Suite 101, Dallas, TX	

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 entrance conference was held with the laboratory representatives. The survey process was discussed and survey forms were provided. An opportunity for questions and comments was given. Noted deficiency and plans of correction were discussed with the laboratory representatives at the exit conference. The laboratory representatives were given an opportunity to provide evidence of compliance with the noted deficiency, and no such evidence was provided prior to survey exit. The facility was found to be in COMPLIANCE with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider /supplier, the State Survey Agency (SA) should be notified immediately.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory policy, laboratory quality control records, and confirmed in staff interview, the laboratory failed to document the intended reactivity for Hematoxylin and Eosin (H & E) staining to ensure predictable staining characteristics of quality control slides for Hematoxylin and Eosin (H & E) staining on each day of patient testing from 06/17/2020 to 01/22/2021, Findings included: 1.

	The laboratory policy titled "H&E Staining Procedure for Frozen Tissue Sections" (Approved by the laboratory director 01/27/2020) stated, "Quality Control: Stains are filtered daily and grossly examined for any evidence of contaminants or precipitates ...." The policy failed to define the intended reactivity for Hematoxylin and Eosin (H & E) staining to ensure predictable staining characteristics of quality control slides. 2. The laboratory quality control record titled "Hematoxylin and Eosin Staining-Quality Control" provided the following documentation: "Slide #; Date; Time; Accept; Unaccept; Physician; Action Taken" The quality control record failed to define the intended reactivity for Hematoxylin and Eosin (H & E) staining to ensure predictable staining characteristics of quality control slides. 3. In an interview on 03/04/2021 at 10:40 am in the office, the histotechnician was asked to explain the H&E control slide procedure and to provide documentation of the intended reactivity for the H&E stain. She stated that the first stained slide each day of patient testing was used as the quality control slide. No documentation was provided for the intended reactivity for the H&E stain. This confirmed the above findings.