Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1099774	01/10/2023
Name of Provider or Supplier	**Street Address, City, State**	
Surgical Dermatology Associates	4851 South I-35, Suite 101, Corinth, 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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found in compliance with applicable CLIA Conditions, 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 CMS Southern Operations Branch-Dallas for referral to the Office of Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on review of laboratory's policies and procedures, review of the laboratory's twice annual accuracy verification [proficiency testing (PT)] records for 2021 and 2022 and staff interview it was determined the laboratory failed to document evaluation of 24 of 58 reviewed PT results. Findings included: 1. Review of laboratory's policies and procedures revealed: a. From policy "Quality Assurance": "The lab will also submit approximately 5 percent of the quarterly slides to be assessed by another physician." b. From form "Quality assurance/proficiency testing": "Enclosed are frozen slides randomly selected from biopsy and mohs cases diagnosed... I am requesting your professional evaluation to verify diagnosis made..." And, "Diagnosis found to match initial case, circle one: Yes/No" 2. Review of the laboratory's twice annual accuracy verification [proficiency testing (PT)] records for 2021 and 2022 revealed the laboratory failed to document evaluation of the following

	24 of 58 reviewed PT sample results to verify whether the diagnosis was found to match initial case: Event: Fourth quarter of 2021 Sample ID: P21-937 Sample ID: P21-948 Sample ID: P21-966 Sample ID: P21-977 Sample ID: P21-991 Sample ID: P21-1007 Sample ID: P21-1018 Sample ID: P21-1029 Sample ID: P21-1046 Sample ID: P21-1067 Sample ID: P21-1092 Sample ID: P21-1100 Sample ID: P21-1113 Sample ID: P21-1125 Sample ID: P21-1140 Sample ID: P21-1153 Sample ID: W21-1146 There was no documented evaluation to verify if diagnosis was found to match the initial case. Event: Second quarter of 2022 Sample ID: W22-459 There was no documented evaluation to verify if diagnosis was found to match the initial case. Event: Third quarter of 2022 Sample ID: P22-763 There was no documented evaluation to verify if diagnosis was found to match the initial case. Event: Fourth quarter of 2022 Sample ID: P22-922 Sample ID: P22-941 Sample ID: W22-965 Sample ID: W22-980 Sample ID: W22-1170 There was no documented evaluation to verify if diagnosis was found to match the initial case. 3. In an interview on 01/10 /2023 at 1130 hours at the nurse's station, the Laboratory Manager, after review of the data, confirmed the findings.
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 review of the laboratory's policies and procedures, review of the laboratory's quality control (QC) records for January to December of 2022, review of patient test records and staff interview it was determined the laboratory failed to document Hematoxylin and Eosin (H&E) stain acceptability/intended reactivity after corrective action for one of one instance corrective action was taken during slide staining. Findings included: 1. Review of laboratory's policy "Quality Control Policies and Documentation" revealed: "The stains are checked each day for intended reactivity. A control slide is prepared and approved by the physician prior to any testing. The approval is recorded on a QC log." 2. Review of the laboratory's QC records for January to December of 2022 revealed the laboratory documented the following corrective action on 06/27/2022: "Water rinse not turned on - fixed after initial slides" 3. Further review of the QC records for 06/27/2022 revealed no documentation of the stain acceptability/intended reactivity after corrective action was performed. 4. Review of patient test records for 06/27/2022 revealed the following patients' samples were tested without documentation of stain acceptability/intended reactivity for that day: Mohs #: # of Slides: 555 3 556 3 557 7 558 18 559 4 560 2 561 6 562 6 563 5 564 2 565 2 566 2 567 4 568 4 569 4 570 2 Legend: Mohs - Micrographically orieted histographic surgery # - number 5. In an interview on 01/10/2023 at 1210 hours at the nurses station, the Laboratory Manager, after review of the data, confirmed the findings.