Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0920969	11/08/2021
Name of Provider or Supplier	**Street Address, City, State**	
Dermsurgery Associates	6700 West Loop South, Suite 450, Bellaire, 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 to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended.
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 the review of the laboratory's policy, QC logs from 1/1/21-10/31/21, patient result logs from 1/1/21 to 10/31/21, and confirmed in an interview found the laboratory failed to document stain QC acceptability for 30 of 30 days reviewed for two of three stains: H&E and T-BLUE. The findings were: 1. Review of the laboratory's policy titled "F. Staining Procedures" under 1. Control Slides revealed "The first frozen section of the day (tumor tissue from the first lesion) serves as the stain control slide. It is checked by the histotechnician first and by the surgeon /pathologist when he/she becomes available." 2. Further review of the laboratory's policy titled "F. Staining Procedures revealed the laboratory uses three stains: H&E, T-Blue, and MART-1. 3. Random review of stain QC logs from 1/1/21-10/31/21 revealed no documentation of stain QC acceptability for H&E and T-Blue by surgeon /pathologist for 30 of 30 days reviewed. 1/6/21 1/19/21 1/21/21 2/2/21 2/3/21 2/23/21

	3/3/21 3/16/21 3/18/21 4/8/21 4/13/21 4/23/21 5/4/21 5/11/21 5/19/21 6/15/21 6/17/21 6/29/21 7/2/21 7/15/21 7/22/21 8/11/21 8/17/21 8/18/21 9/3/21 9/21/21 9/24/21 10/5 /21 10/8/21 11/4/21 4. Random review of patient result log for the above dates revealed 52 patients with stain slides. 1/6/21 Case# 21DSG006 1/19/21 Case# 21DSG056, 21DSW015 1/21/21 Case# 21DSW018 2/2/21 Case# 21DSG106, 21DSG108 2/3/21 Case# 21DSG111, 21DSG119 2/23/21 Case# 21DSG167, 21DSW45 3/3/21 Case# 21DSG194, 21DSG195 3/16/21 Case# 21DSG248, 21DSG249 3/18/21 Case# 21DSG263 4/8/21 Case# 21DSG340, 21DSW096 4/13/21 Case# 21DSG355, 21DSW100 4/23/21 Case# 21DSG402, 21DSG403 5/4/21 Case# 21DSG440, 21DSW123 5/11/21 Case# 21DSG455, 21DSW134 5/19/21 Case# 21DSG493 6/15/21 Case# 21DSG630, 21DSW168 6/17/21 Case# 21DSG650, 21DSW172 6/29/21 Case# 21DSG710, 21DSW180 7/2/21 Case# 21DSG733, 21DSG737 7/15/21 Case# 21DSG787, 21DSW194 7/22/21 Case# 21DSG824, 21DSW202 8/11/21 Case# 21DSG917 8/17/21 Case# 21DSG945, 21DSG985 8/18/21 Case# 21DSG951 9/3/21 Case# 21DSG1035, 21DSG1041 9/21/21 Case# 21DSG1077, 21DSW240 9/24/21 Case# 21DSG1085, 21DSG1089 10/5/21 Case# 21DSW258 10/8/21 Case# 21DSG1133 11/4/21 Case# 21DSW291, 21DSW296 5. An interview with the histotechnician on 11/8/21 at 10:06 am in the lab confirmed the above findings. The histotechnician confirmed the slide QC acceptability was not documented by pathologists. Key: QC=Quality Control H&E=Hematoxylin-Eosin Stain T-BLUE=Toluidine Blue Stain MART-1=Melanoma antigen recognized by T cells or Melan-A