Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2150708	09/25/2020
Name of Provider or Supplier	**Street Address, City, State**	
Dermsurgery Associates-Sugar Land	1415 Highway 6 Soiuth, C-400, Sugar Land, 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 deficiency and plans of correction were discussed with the laboratory representative at the entrance and exit conferences. The facility representative was 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.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on direct observation, review of laboratory policies, and confirmed in interview of facility personnel, the laboratory failed to follow its own policy for labeling Mohs slides. The findings were: 1. Review of the laboratory's policy, "Labeling of Frozen Section Slides" stated: "A. Slides are to be labeled before frozen sections are cut 1. Information to be written with a slide marking pen on the frosted end of the slide must be obtained from the Polaroid photo that was delivered with the tissues or the Digital Photo in the electronic medical record. a. Line 1 - Surgery Accession (Case) # and lesion designation (A, B, etc.) b. Line 2 - Patient name: Last Name, First Initial (first

	slide of each case) c. Lower Right Corner - Stage # (Stage 1 is understood and is not noted on the slide)/Tissue Piece #..." 2. Surveyor observation on September 25, 2020 at 14:30 hours in the break room found 2 of 25 slides labeled with patient first initial, last name, and date only. 3. The laboratory failed to follow its own slide labeling policy. 4. An interview with the practice manager and Histotechnologist on September 25, 2020 at 14:35 hours in the break room confirmed the findings.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on direct observation and interview with facility personnel, the laboratory failed to label secondary aliquot containers of stains and reagents with lot numbers and expiration dates. The findings were: 1. Surveyor observation on September 25, 2020 at 13:20 hours in the laboratory found 1 of 1 amber colored secondary containers of Toludine Blue not labeled with lot number or expiration date. 2. Surveyor observation on September 25, 2020 at 13:20 hours in the laboratory found 14 of 14 stains and regents on the autostainer not labeled with lot number or expiration date. 3. An interview with the Histotechnologist on September 25,2020 at 13:20 hours in the laboratory confirmed the findings. She revealed the Toludine Blue was a reagent that was made from powder.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on surveyor observation and confirmed in interview of facility personnel, the laboratory failed to ensure expired reagents were not available for use in patient testing. The findings were: 1. Surveyor observation on September 25, 2020 at 13:15 hours in the laboratory found the following expired reagent: 10% KOH (Potassium Hydroxide) Lot Number: 1808804 Expiration date: 03-29-2019 10% KOH (Potassium Hydroxide) Lot Number: 1735206 Expiration date: 12-18-2018 2. An interview with the Histotechnologist on September 25, 2020 at 13:20 hours in the laboratory confirmed the findings. She confirmed that only Mohs was performed at this location and no patient KOH testing was performed.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of laboratory records and confirmed in interview of facility personnel, the laboratory failed to establish and follow written policies and procedures for ongoing evaluation of its analytic systems. The findings were: 1. Review of the laboratory's Mohs Patient Testing Log in comparison with patient slides and patient electronic records found that 3 of 10 patient records reviewed did not all match. The patient testing log (documented in Microsoft Excel) found the case numbers on the log sheet did not match the slides and case number found in the patient's electronic medical record. 2. Review of the laboratory's policies and procedures found the laboratory failed to establish and follow a quality assurance policy that would identify and correct when the patient log sheet does not match patient slides and the patient electronic medical record. 3. An interview with the practice manager and the Histotechnologist on September 25, 2020 at 15:00 hours in the break room confirmed the findings. They agreed the information on the Excel spreadsheet did not match. They confirmed it was due to a clerical error not a patient identification error, and went on to say they would reconcile the records.