Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D1089854	10/21/2020
Name of Provider or Supplier	**Street Address, City, State**	
Dermasurgery Center Llc, The	6411 Perkins Rd, Ste 100, Baton Rouge, LA	

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	A Certification Survey was performed on October 21, 2020 at The Dermasurgery Center, LLC, CLIA ID # 19D1089854. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
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 personnel, the laboratory failed to label marking dyes stored in secondary containers with identity, expiration date, and storage requirements. Findings: 1. Direct observation by surveyor during laboratory tour on October 21, 2020 at 9:12 am revealed the following marking dyes stored in "10 % neutral buffered formalin" containers: a) Two (2) containers of green dye b) Two (2) containers of blue dye c) One (1) container of yellow dye d) One (1) container of red dye 2. In interview on October 21, 2020 at 9:27 am, the Histotechnican stated the laboratory discards the 10% formalin and stores marking dyes in the containers. The Histotechnican confirmed the secondary containers were not labeled with its contents.
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 direct observation and interview with personnel, the laboratory failed to ensure supplies did not exceed their expiration dates. Findings: 1. Direct observation by surveyor during the laboratory tour on October 21, 2020 at 9:12 am revealed the following expired items: a) Yellow Tissue Marking Dye, Lot 044067, Expiration date: 01/18, Quantity: one (1) bottle 1/4 full b) Avantik Biogroup OCT Embedding Matrix for Frozen Sections, Lot 03811957, Expiration date: 2019/08, Quantity: one (1) bottle c) Sakura Tissue Tek OCT Compound, Lot 7908-00, Expiration date: 2020-01-31, Quantity: one (1) bottle 2. In interview on October 21, 2020 at 9:55, the histotechnician confirmed the identified items were expired.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of patient final test reports and interview with personnel, the laboratory failed to specify the laboratory location where testing was performed for four (4) of six (6) frozen section patient final test reports reviewed. Findings: 1. Review of random selection of patient final test reports for frozen sections revealed the addresses for three (3) different laboratory locations were included on the reports. 2. Review of the following four (4) patient final test reports for frozen sections revealed the specific laboratory's location that performed the testing was not indicated: Patient 19bx41 Patient 19bx-99 Patient 20bx-10 Patient 20bx-104 3. In interview on October 21, 2020 at 9:55 am, the Histotechnican confirmed the specific laboratory location that performed the testing was not indicated on the identified patient final reports. 4. Review of the laboratory's test menu revealed the laboratory performs 100 frozen sections annually.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed test methods as required. Findings: 1. The laboratory failed to label marking dyes stored in secondary containers with identity,

	expiration date, and storage requirements. Refer to D5415. 2. The laboratory failed to ensure supplies did not exceed their expiration dates. Refer to D5417.
D6098	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(8) The laboratory director must ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure final reports included required pertinent information. Refer to D5805.