Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D2060138	11/17/2021
Name of Provider or Supplier	**Street Address, City, State**	
Skin Surgery Centre Llc	2581 Florida Street, Suite C, Mandeville, 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 Recertification survey was performed on November 17, 2021 at The Skin Surgery Centre, LLC, CLIA ID # 19D2060138. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, maintenance logs, and interview with personnel, the laboratory failed to establish complete maintenance policies for the air vent/fume hood. Findings: 1. Review of the laboratory's "Air Vent/Fume Hood Policy" revealed the following tasks: a) "Dust air vent monthly, document" b) "Replace filter as required by manufacturer, document" 2. Review of the laboratory's "Fume Hood/Air Vent Log" for 2019, 2020, and 2021 revealed the following maintenance tasks: a) 2019: "Dust air vent monthly, document. Replace filter as required by manufacture [sic], document. Grounding to be checked and documented annually." b) 2020: "Dust air vent monthly, document. Replace filter as required by manufacture [sic], document." c) 2021: "Dust air vent monthly, document. Replace filter as required by manufacture [sic], document. Grounding to be checked and documented annually." 3. In interview on November 17, 2021 at 11:01 am, the Laboratory Manager stated she was unsure why grounding was listed as a

	maintenance task on the 2021 log sheets, as the laboratory discontinued performing that task. The Laboratory Manager confirmed the laboratory's policy differs from tasks indicated on the log sheets.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, cryostat temperature logs, and interview with personnel, the laboratory failed to document corrective actions performed when the cryostat temperature was documented outside of acceptable range for six (6) of 331 days reviewed in June 2019 through December 2020. Findings: 1. Review of the laboratory's "Cryostat Maintenance" policy revealed "Console temperature is recorded daily. The cryostats should be maintained at -20*C to no colder than -30*C [sic] for best sectioning. Any variance out of range will be recorded and reported to the supervisor, immediately. An incident report will be filled out." 2. Review of the laboratory's cryostat temperature logs revealed the following: "The cryostats should be maintained at -20*C to -30*C [sic] for best mohs sectioning. Any variance out of range will be recorded and reported to the supervisor, immediately. If the range variance cannot be repaired, the console will not be used until serviced." 3. Review of the laboratory's cryostat temperature logs for 2019 and 2020 revealed the following six (6) dates the cryostat's temperature exceeded acceptable limits without documented corrective actions: November 1, 2019 recorded temperature -31 degrees Celsius June 3, 2020 recorded temperature -32 degrees Celsius June 4, 2020 recorded temperature -32 degrees Celsius June 9, 2020 recorded temperature -32 degrees Celsius July 17, 2020 recorded temperature -32 degrees Celsius December 23, 2020 recorded temperature -31 degrees Celsius 4. In interview on November 17, 2021 at 10: 17 am, the Laboratory Manager confirmed the laboratory did not have documentation of corrective actions for temperatures that exceeded acceptable limits.
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 the laboratory's policies, cryostat temperature logs, and interview with personnel, the laboratory failed to follow written procedures to monitor, assess,

	and correct problems identified with the analytic system for cryostat temperature documentation for twenty three (23) of 534 days reviewed from June 2019 through November 17, 2021. Findings: 1. Review of the laboratory's "Cryostat Maintenance" policy revealed "Console temperature is recorded daily. The cryostats should be maintained at -20*C to no colder than -30*C [sic] for best sectioning. Any variance out of range will be recorded and reported to the supervisor, immediately. An incident report will be filled out." 2. Review of the laboratory's 2019, 2020, and 2021 cryostat temperature logs revealed the laboratory changed temperature values to meet acceptability criteria for the following twenty three (23) days: November 4, 2019 -30 C written over documented temperature of -32 C November 19, 2019 -30 C written over documented temperature of -32 C November 22, 2019 -30 C written over documented temperature of -32 C December 3, 2019 -30 C written over documented temperature of -32 C December 10, 2019 -30 C written over documented temperature of -32 C December 13, 2019 -30 C written over documented temperature of -32 C January 9, 2020 -30 C written over documented temperature of -32 C January 14, 2020 -30 C written over documented temperature of -32 C January 17, 2020 -30 C written over documented temperature of -32 C February 7, 2020 -30 C written over documented temperature of -32 C February 28, 2020 -30 C written over documented temperature of -32 C March 6, 2020 -30 C written over documented temperature of -32 C March 13, 2020 -30 C written over documented temperature of -32 C May 6, 2020 -30 C written over documented temperature of -32 C May 8, 2020 -30 C written over documented temperature of -32 C August 7, 2020 -30 C written over documented temperature of -32 C August 13, 2020 -30 C written over documented temperature of -32 C August 21, 2020 -30 C written over documented temperature of -32 C October 28, 2020 -30 C written over documented temperature of -31 C December 1, 2020 -30 C written over documented temperature of -32 C January 25, 2021 -30 C written over documented temperature of -32 C April 9, 2021 -30 C written over documented temperature of -32 C July 22, 2021 -30 C written over documented temperature of -32 C 3. In interview on November 17, 2021 at 10:17 am, the Laboratory Manager confirmed the identified documented cryostat temperatures were written over without documented action by the laboratory.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was maintained to assure the quality of laboratory services provided. Refer to D5791.
D6095	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6) The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system. This STANDARD is not met as evidenced by:

	Based on review of maintenance logs and interview with personnel, the Laboratory Director failed to ensure maintenance policies were established to ensure acceptable levels of test performance. Refer to D5433.
D6096	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7) The laboratory director must ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure corrective actions were taken and documented when deviations from laboratory's policies occurred. Refer to D5781.