Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2046931	08/10/2022
Name of Provider or Supplier	**Street Address, City, State**	
Center For Skin Surgery Laboratory	46325 W 12 Mile Road Suite 370, Novi, MI	

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
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: . Based on lack of documentation and interview with Testing Personnel (TP) #2, the laboratory failed to perform and document the function checks as required for the room temperature for 18 (March 2021 to August 2022) of 18 months of patient testing. Findings include: 1. A record review on 8/10/2022 at 11:30 am revealed lack of documentation of the room temperature for 18 of 18 months of patient testing. 2. A record review of the "Quality Control Program" policy, under section Test Methods, Equipment, Reagents, Materials and Supplies states "All equipment within the laboratory will be properly maintained according to the manufacturer's specification. "All maintenance and repairs will be recorded and maintained by the laboratory personnel and will be review by the Laboratory Director on a periodic basis." 3. An interview on 8/10/2022 at 6/23/2022 at 11:30 am, TP2 confirmed the laboratory failed to perform and document the room temperature.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel

	who performed the test(s). This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel (TP) #2, the laboratory failed to document the time of specimen receipt into the laboratory for 2 (L-21-123 and M-22-061) of 18 Mohs' cases reviewed. Findings include: 1. A review of 18 Mohs' cases revealed 2 cases did not have the time received in the laboratory documented on the Mohs' map as follows: a. K-21-123, stages I and II b. M-22-061, stages I, II, III, and IV 2. An interview on 8/10/2022 at 11:30, TP2 confirmed the time of specimen receipt in the laboratory had not been documented. ***Repeat Deficiency from the 9/17/2018 survey***
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel (TP) #2, the laboratory failed to establish a system to ensure the transcribed Mohs' surgery site was accurately reported for 3 (M-21-702, M-22-165, and M-22-233) of 18 Mohs cases reviewed. Findings include: 1. A record review revealed for 3 of 18 Mohs' cases reviewed, the surgical site on the pre-op biopsy report, the Mohs' map, Mohs' log, and the final report in the electronic medical record (EMR) system are not consistently transcribed throughout the Mohs' survey process as follows: a. M-21-702 performed on 12/18 /2021 i. Pre-op biopsy report, Mohs' map, and the EMR report - left inferior lateral forehead ii. Mohs' log - left lateral forehead b. M-22-165 performed on 4/18/2022 i. Pre-op biopsy report, Mohs' map, and the EMR report - left inferior lateral forehead ii. Mohs' log - left inferior forehead c. M-22-233 performed on 6/13/2022 i. Pre-op biopsy report, Mohs' map, and the EMR report - left inferior central malar cheek ii. Mohs' log - left inferior central cheek 2. An interview on 8/10/2022 at 11:30 am, TP2 confirmed the locations on the pre-op biopsy report, Mohs' map, Mohs' log, and the final EMR report were not consistent with the original biopsy site throughout the survey process.