Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2046931	09/17/2018
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
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: . Based on operator's manual review and interview, the laboratory failed to follow the manufacturer's operator's manual to monitor and record the humidity readings in the laboratory for 24 (September 2016 to September 2018) of 24 months reviewed to ensure reliable Leica CM 1510S cryostat operation. Findings include: 1. On September 17, 2018 at 11:00 AM, document review of the maintenance log for temperatures revealed there was no monitoring and documenting of the humidity for 24 (September 2016 to September 2018) of 24 months reviewed. 2. During the interview on September 17, 2018 at 11:00 AM, the laboratory director confirmed the humidity readings were not monitored and documented.
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 observation and interview, the laboratory failed to label the Mohs' tissue marking dyes (yellow, green, red, and blue) with the contents, storage requirements, preparation, and expiration dates for the poured off inks stored in smaller containers. Findings include: 1. On September 17, 2018 at approximately 9:20 AM during a tour of the laboratory, the surveyor observed the Mohs' tissue marking dyes (yellow, green, red, and blue) poured off into smaller containers. There was no documentation on the containers with the contents, storage requirements, preparation, or expiration dates when the dyes were poured into the containers. 2. During the interview on September 17, 2018 at approximately 9:20 AM, the laboratory director confirmed the poured off marking dye containers were no labeled.
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 observation and interview, the laboratory failed to use nine (violet, green, blue, black, orange, red, red, and yellow) of 13 Mohs' tissue marking dyes before the manufacturer's expiration date. Findings include: 1. During a tour of the laboratory on September 17, 2018 at approximately 9:20 AM, the surveyor observed the Mohs' tissue marking dyes located in the cupboard in use past the manufacturer's expiration dates recorded on the label as follows: a. violet - lot 37796 expiration date 02/2017 b. green - lot 044507 expiration date 01/2018 c. yellow - lot 05089 expiration date 09 /2016 d. blue - lot 044802 expiration date 02/2018 e. black - lot 36886 expiration date 03/2017 f. orange - lot 38887 expiration date 04/2017 g. red - lot 046279 expiration date 04/2018 h. red - lot 7137 expiration date 08/2018 i. yellow - lot 044509 expiration date 01/2018 2. During the interview on September 17, 2018 at approximately 9:20 AM, the laboratory director confirmed the dyes had exceeded the manufacturer's expiration dates.
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, the laboratory failed to 1) maintain a record system that included the identity of the testing personnel performing the Mohs' microscopic tissue examination for two (#14 and #16) of 20 patient charts audited and the microscopic frozen section interpretation for one (#18) of 20 patient charts audited and 2) the date and time of specimen receipt into the laboratory for the Mohs' tissue and the frozen section specimens for 20 (#1 - #20) of 20 patient charts audited. Findings include: 1. On September 17, 2018 at 12:00 PM, record review of patients

	charts revealed the laboratory did not include the identity of the testing personnel who performed the Mohs' microscopic tissue examination and the frozen section interpretation for two of 20 and one of 20 patient charts audited. 2. On September 17, 2018 at 12:00 PM, record review revealed the laboratory did not have any record of the time the Mohs' tissue and the frozen section specimens were received into the laboratory for examination. 3. During the interview on September 17, 2018 at 12:00 PM, the laboratory director confirmed the identity of the testing personnel and the time of specimen receipt into the laboratory was not available on the patient's final test reports.