Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D0701078	05/16/2019
Name of Provider or Supplier	**Street Address, City, State**	
Central Ohio Skin & Cancer, Inc	430 Altair Parkway, Suite 210, Westerville, OH	

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
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 review of the laboratory's policies and procedures and an interview with the Laboratory Director (LD), the laboratory failed to have a written policy and procedure available to laboratory personnel for all oral pathology testing procedures performed. This deficient practice had the potential to affect all oral pathology specimens tested. Findings Include: 1. Review of the laboratory's policies and procedures, provided on the date of survey, did not find any mention of a policy and procedure for the oral pathology test system. 2. The Surveyor requested the laboratory's written policy and procedure for oral pathology testing from the LD. The LD confirmed the laboratory did not establish oral pathology written policies and procedures, and was unable to provide the requested documentation on the date of survey. The interview occurred on 05/16/2019 at 11:30 AM.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in

	electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on direct observation and an interview with the Nurse Manager (NM), the laboratory failed to follow the manufacturer's instructions for the storage temperatures of Thermo-Scientific hematoxylin, reagent alcohol, 100% dehydrant and SurgiPath decalcifier II solutions. This deficient practice had the potential to affect 17,770 patients tested in the subspecialty of oral pathology and histopathology. Findings Include: 1. Direct observation found the following storage requirements listed on each container: Thermo Scientific hematoxylin 15-30 C Thermo Scientific reagent alcohol 15-30 C Thermo Scientific 100% dehydrant 15-30 C SurgiPath decalcifier II 15-30 C C; degrees Celsius 2. The NM confirmed the laboratory did not monitor the storage area for the Thermo-Scientific hematoxylin, reagent alcohol, 100% dehydrant and SurgiPath decalcifier II solutions and did not follow the manufacturers instructions. The interview occurred on 05/14/2019 at 11:00 AM.