Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D2046680	05/31/2018
Name of Provider or Supplier	**Street Address, City, State**	
Ssm Health Dermatology	9720 Broadway Extension, Oklahoma City, OK	

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	The findings were reviewed with the histotechnician at the conclusion of the survey.
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 a review of records, manufacturer's instructions, and interview with the histotechnician, the laboratory failed to ensure the manufacturer's environmental specifications were met. Findings include: (1) At the beginning of the survey, the histotechnician stated to the surveyor, the laboratory performed frozen sections of tissues obtained during Mohs surgical procedures and from biopsies. The tissues were processed using two Avantik Cryostat QSII cryostats and stained with H&E (Hematoxylin and Eosin) and examined microscopically for diagnosis; (2) The surveyor reviewed the manufacturer's environmental requirements for the cryostats. The manufacturer required a humidity of less than 60%; (3) Records were reviewed from 14 months (July, August, September, and December 2016; January, April, May, June, July, October, and December 2017; and February, March and April 2018) and the surveyor identified 3 days of patient testing when the humidity was unacceptable at 60%: (a) July 2016: Day 22 (b) August 2016: Day 4 (c) July 2017: Day 31 (4) Although corrective action had been taken (shut doors, turned air conditioning down), there was no documentation the humidity was checked to ensure the corrective action had been effective in obtaining an acceptable humidity; (5) The surveyor reviewed the

	findings with the histotechnician who stated to the surveyor the laboratory did not check the humidity after the corrective action was taken to ensure the manufacturer's humidity requirement had been met.
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 a review of records and interview with the histotechnician, the laboratory failed to ensure test reports included positive patient identification. Findings include: (1) At the beginning of the survey, the histotechnician stated to the surveyor, the laboratory performed frozen sections of tissues obtained during Mohs surgical procedures and from biopsies. The tissues were stained with H&E (Hematoxylin and Eosin) and examined microscopically for diagnosis; (2) During the survey, the surveyor reviewed H&E slides and patient test reports for 15 biopsy and Mohs surgical cases (24 slides were reviewed). The surveyor identified the laboratory used incorrect specimen identification numbers: (a) Patient #1-Testing performed on 04/24 /17 (i) The specimen identification number documented in the patient test log was M17R-192 (ii) The specimen identification number documented on the patient test report was M17R-193 (iii) The specimen identification number on the H&E slides was M17R-193 (b) Patient #2-Testing performed on 02/15/18 (i) The specimen identification number documented in the patient test log was M18R-096 (ii) The specimen identification number documented on the patient test report was R-096 (3) The surveyor asked the histotechnician to explain how the laboratory identified specimen samples. The histotechnician explained each day specimen identification numbers were written in successive order in the patient test log. This specimen identification number was assigned to the patient samples, slides, and reports to maintain consistent identification; (4) The surveyor reviewed the findings with the histotechnician who stated to the surveyor the laboratory failed to document the correct specimen identification number for positive identification on the patient test report and patient slides listed above.