

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0953867	(X3) Date Survey Completed 05/23/2019
Name of Provider or Supplier Ou Health Partners Dermatology	Street Address, City, State Nicholson Tower, 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 recertification survey was performed 05/23/19. The laboratory was found to be in compliance with a standard-level deficiency cited. The findings were reviewed with the senior clinic manager and the Mohs histology technician at the conclusion of the survey.
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the Mohs histology technician, the laboratory failed to follow the manufacturer's instructions. Findings include: (1) At the beginning of the survey, the Mohs histology technician stated to the surveyor the laboratory performed microscopic examination of frozen sections from tissues obtained during Mohs surgery. The tissue was frozen and cut using two Leica CM1850 Cryostats, then the sections were mounted on slides, dried, stained with H&E (Hematoxylin and Eosin), and interpreted for diagnosis; (2) The surveyor reviewed the laboratory's humidity records from 09/01/17 through 05/23/19. The laboratory's acceptable humidity range listed on the logs was "20-85%;" (3) The surveyor then reviewed the manufacturer's storage requirements for the cryostats. The manufacturer required a humidity that did not exceed 60%. The surveyor identified the laboratory's acceptable range would allow for humidity to be higher than the manufacturer's specification; (4) The surveyor reviewed the findings with the Mohs histology technician, who stated to the surveyor the laboratory's acceptable humidity range did not meet the manufacturer's specification for humidity.</p>