

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0689884	(X3) Date Survey Completed 08/26/2019
Name of Provider or Supplier Skin Cancer Center	Street Address, City, State 2644 Nw 63rd St, 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 08/26/2019. The laboratory was found in compliance with a standard-level deficiency cited. The findings were reviewed with histotechnologist #1 at the conclusion of the survey.
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records, written policy, and interview with histotechnologist #1, the laboratory failed to perform the manufacturer's required maintenance procedures on the cryostat. Findings include: (1) At the beginning of the survey, histotechnologist #1 stated to the surveyor the laboratory prepared frozen sections from tissues obtained during Mohs surgeries using the Leica CM1520 Cryostat. The sections were stained with H&E (Hematoxylin & Eosin), then examined microscopically by a pathologist for interpretation; (2) The surveyor reviewed the manufacturer's maintenance instructions for the cryostat, which were: (a) Monthly: Oil the flywheel and moving components (b) Monthly: Defrost the cryostat or when ice accumulates (3) The surveyor reviewed the maintenance records for the Leica CM1520 cryostat for 7 months in 2019 (January through July 2019) and identified the monthly maintenance procedures had not been documented as having been performed between 05/03/19 and 07/03/19; (4) The surveyor then reviewed the laboratory written policy, "Equipment Control Cryostat." It stated: (a) "4. Defrosting of machine is done monthly"; (b) "8. The flywheel and moving components on the cryostat are oiled as recommended by the manufacturer every month"; (c) "12. Every action is documented in the</p>

maintenance record form". (5) The surveyor reviewed the findings with histotechnologist #1 who stated to the surveyor, the monthly maintenance procedures listed above had been performed but had not been documented.