

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D2151711	(X3) Date Survey Completed 12/28/2022
Name of Provider or Supplier Kentucky Skin Cancer Center	Street Address, City, State 1818 Wallace Ct, Suite 301, Bowling Green, KY	
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	A recertification survey was conducted on 12/28/2022 and the facility was found not to be in substantial compliance with the laboratory requirements at 42 CFR Part 493, with deficiencies cited.
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on interview, record review, and review of the facility's policies, the facility failed to ensure the proficiency and accuracy of histopathology specimens were verified at least twice annually. The findings include: Review of the facility's policy titled, "Proficiency Testing", undated, revealed "Semi-annually, the tech [technician] or Risk Manager will send two (2) cases containing the original slides, label it with only the surgical case number, and send it out for a microscopic examination by a Board Certified Dermatologist. No differential diagnosis will be offered with the specimen. The slide may be labeled 'Proficiency Test' by the sending laboratory for the records of the reference laboratory." The policy further indicated, "Results of each Proficiency Test will be entered in a log and kept in the laboratory management manual, as part of its permanent records." A review of the facility's proficiency test records revealed only one (1) peer review evaluation was performed for 2022. Interview with Testing Personnel #1, on 12/28/2022 at 11:53 AM, revealed only one (1) proficiency test peer evaluation was performed in 2022.</p>
D5433	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p> <p>For equipment, instruments, or test systems developed in-house, commercially</p>

available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:

Based on observation and interview, the facility failed to perform maintenance of the microscope used to perform examination of specimens from 10/2019 through 12/2022. The findings include: Observation during the laboratory tour, on 12/28/2022 at 11:40 AM, revealed the Laboratory Director (LD) was reading a slide on the microscope. The last preventative maintenance was noted to have been performed 10/2019. Interview with the LD, on 12/28/2022 at 12:30 PM, revealed there had been no preventative maintenance performed on the microscope between 10/2019 and 12/2022.