

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D2151711	(X3) Date Survey Completed 08/13/2024
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 08/13/2024. The facility was found not to be in compliance with the laboratory requirements of 42 CFR Part 493 with deficiencies cited.
D5601	<p>HISTOPATHOLOGY CFR(s): 493.1273(a)(f)</p> <p>(a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section.</p> <p>This STANDARD is not met as evidenced by: Based on facility policy reviews, facility document reviews, and confirmed in staff interview; the facility failed to assess and document the quality control performance of a Hematoxylin and Eosin (H&E) histochemical stain used in the evaluation of Mohs micrographic surgical slides at the start of each day of patient testing. Specifically, the facility failed to document daily H&E slide stain quality control assessments for 88 of 192 days of Mohs patient testing reviewed. Findings included: An undated facility policy titled, "Quality Assurance for Routine Stains," revealed, "1. A quality control slide will be run each day the lab operates." The policy revealed, "The lab director will determine whether the stain is acceptable for the day. Each QC [quality control] will be logged on the stain QC chart. Any corrections needed for that day will be addressed at that particular time and all changes will be documented." An undated facility policy titled, "Stain Maintenance," revealed, "8. The first case of mohs day will be documented as the quality control and logged on the QC sheet. 9. Any deficiencies or corrections will be documented and corrected." An undated facility policy titled, "Stain Maintenance Auto-Stainer," revealed, "10. A QC</p>

worksheet is documented daily on the stain quality and any corrections or changes made." An undated document titled, "Hematoxylin and Eosin Stain," revealed, "Quality Assurance: The first case submitted to the mohs lab which consists of NORMAL tissue will be stained for H&E and documented on the control sheet as the QA [quality assurance]." A comparative review of completed Mohs patient logs versus daily Mohs slide H&E quality control logs, found in the binders labeled "Mohs Records 2023" and "Mohs Records 2024" for the timeframe from 01/01/2023 through 08/13/2024, when compared to a standard calendar for 2023 and 2024, revealed the following statistics: - Total number of days of Mohs patient testing: 192 - Number of daily H&E slide stain quality control assessments not found: 88 - Total number of Mohs patient testing cases: 832 - Number of Mohs patient testing cases with no H&E slide stain quality control assessments documented: 396 During an interview on 08/13/2024 at 8:45 AM, the Laboratory Director confirmed that the H&E slide quality control results had not been documented on a daily basis and that Mohs patient testing had been performed despite that fact.