

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D2289220	(X3) Date Survey Completed 03/12/2025
Name of Provider or Supplier Kentucky Skin Cancer Center	Street Address, City, State 2915 New Hartford Road, Owensboro, 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	An Initial Survey was initiated on 03/12/2025 and concluded on 03/12/2025. 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 review of facility documents, review of facility's policies, and an interview, the laboratory 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 (slides of tissue samples removed by a surgeon) at the start of each day of patient testing. Specifically, the facility failed to document daily H&E slide stain quality control assessments for 34 of 200 days of Mohs patient testing reviewed. Findings included: An undated facility document titled, "Daily Routine," revealed, "2. Make QA [quality assurance] slide for Hematoxylin and Eosin." An undated document titled, "Hematoxylin and Eosin [H&E] Stain," revealed, "Quality Assurance: The first case submitted to the mohs [sic] lab which consists of NORMAL tissue will be stained for H&E and documented on the control sheet as the QA." An undated facility policy titled, "Quality Control Policies and Documentation," revealed, "3. The stains are checked each day for intended reactivity. A control slide is prepared and approved by the physician prior to any testing. The approval is recorded on a QC [quality control] log." An undated facility policy titled, "Stain Maintenance Auto-</p>

Stainer," revealed, "10. A QC worksheet is documented daily on the stain quality and any corrections or changes made." An undated facility policy titled, "Stain Maintenance," revealed, "8. The first case of each mohs [sic] 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, "Quality Assurance for Routine Stains," revealed, "1. A quality control slide will be run each day the lab operates." The policy also revealed, "The lab director will determine whether the stain is acceptable for the day. Each QC 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." Laboratory patient logs and "Quality Control Staining" logs for the timeframe from 12/06/2021 through 03/12/2025 revealed Mohs H&E slide stain quality control assessments were not found on 34 days of patient testing: 12/06/2021, 02/14/2022, 06/20/2022, 11/14/2022, 07/25/2023, 09/05/2023, 11/13/2023, 11/14/2023, 12/18/2023, 01/18/2024, 02/08/2024, 02/12/2024, 02/19/2024, 02/20/2024, 02/26/2024, 03/11/2024, 05/09/2024, 05/13/2024, 05/16/2024, 05/20/2024, 06/03/2024, 06/10/2024, 06/13/2024, 06/17/2024, 07/08/2024, 10/02/2024, 10/15/2024, 10/17/2024, 11/20/2024, 12/04/2024, 12/05/2024, 12/11/2024, 12/12/2024, and 01/02/2025. During an interview on 03/12/2025 at 11:45 AM, Histotechnician #1 confirmed the requirement for performing and documenting slide stain quality control was firmly established in procedure but had not been consistently performed.