Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2028816	(X3) Date Survey Completed 11/08/2022
Name of Provider or Supplier Dermatology And Skin Cancer Consultants, Pllc	**Street Address, City, State** 701 Medical Park Drive, Humboldt, TN	
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
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of patient accessioning records, and interview with the lead histotech, the laboratory failed to maintain accessioning records that were separate from a sister laboratory in 2020, 2021 and 2022 resulting in the potential for the same accessioning number being issued to multiple cases. The findings include: 1. Observation of the laboratory on 11/8/22 at 7:30 am revealed the laboratory performs testing for histopathology on patient tissue removed during MOHS procedures. 2. During the patient test management review it was noted that the accessioning records for this laboratory were not maintained separately from a sister lab. 3. Interview with the lead histotech on 11/08/22 at 9:15 am confirmed the laboratory did not maintain separate accessioning records for MOHS/histopathology cases that were distinct from a sister laboratory in 2020, 2021, and 2022.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) 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. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the lab director, the

	laboratory failed to ensure the verification of accuracy for its' histopathology patient testing was performed twice a year in 2020, 2021, and 2022. The findings include: 1. Review of laboratory verification of accuracy records for histopathology revealed that verification of accuracy was not performed twice in 2020, 2021, and 2022. 2. Interview with the lab director on 11/08/22 at 10:30 am confirmed the laboratory failed to verify the accuracy of its' histopathology procedures twice a year in 2020, 2021, and 2022.
D5609	HISTOPATHOLOGY CFR(s): 493.1273(e)(f) (e) The laboratory must use acceptable terminology of a recognized system of disease nomenclature in reporting results. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on observation of the laboratory, lack of documentation, and interviews with the lead histotech and the laboratory director, the laboratory failed to maintain records of chemicals, stains, and dyes used for processing tissue removed during MOHS surgical procedure and quality assessment when new reagents were opened in 2020, 2021 and 2022. The findings include: 1. Observation of the laboratory on 11/08/22 at 7:30 am revealed multiple chemicals, stains (Hematoxylin and Eosin), and dyes in use for performing processing, staining, and inking of patient tissue removed during MOHS surgical procedures. 2. There was a lack of historic records for chemicals, stains and dyes to include reagent lot numbers, date opened, expiration date, and stain quality control/quality assessment when the reagents and stains were opened. 3. During an interview with the lead histotech on 11/08/22 at 9:15 am the lead histotech stated that he checked and recorded the lot numbers and expiration dates monthly, but the record is then discarded. 4. Interview with the lab director at 10:30 am confirmed the laboratory failed to maintain historic reagent and quality assessment records that included lot numbers, date opened, expiration date and stain quality assessment when new reagents/stains were opened in 2020, 2021, and 2022.