Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	15D0691800	01/25/2023
Name of Provider or Supplier	**Street Address, City, State**	
Booth Dermatology Group, Pc	12050 N Michigan Rd, Zionsville, IN	

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
D5219	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(2) At least twice annually, the laboratory must verify the accuracy of any test or procedure listed in subpart I of this part for which compatible proficiency testing samples are not offered by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on record reviews and interview, the laboratory failed to verify the accuracy of MOHS Microscopic Surgery (MOHS) testing twice annually in 2021 and 2022. Findings Included: 1. The "Quality Assurance Program" policy, reviewed by the laboratory director on 9/15/2022, read "B. Proficiency Testing The laboratory will be active in a CLIA approved proficiency testing program." The policy did not state proficiency testing must be performed twice annually. 2. The "Slide Exchange Agreement", signed by the laboratory director on 10/25/2022, stated... "Slides will be sent/picked up and brought to 'Laboratory B' for review and diagnosis." The agreement did not mention the slides would be exchanged twice annually. 3. Review of slide exchange documentation labeled "Dermatopathology Proficiency Test" with Laboratory B from 2021 and 2022 revealed the following: a.) Slides were exchanged on 10/15/2021 for 10 cases and was signed by laboratory director on 10/10/2021. b.) Slides were exchanged on 10/26/2022 for 10 cases and was signed by laboratory director on 10/25/2022. 4. During an interview on 1/25/2023 at 2:37 PM, Sp-1 (Laboratory Director) confirmed verification of MOHS testing was not completed in 2021 and 2022.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3)

	Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to label the correct specimen number for one (PT#1) out of eight patients reviewed for MOHS testing. Findings Included: 1."Mohs Surgery Slides" policy signed by laboratory diector on 10 /22/2022, read ,"The slides will be labeled with the mounting number of the patient, correlating to map number." 2. Two patient cases reviewed PT#1 and PT#2 had the specimen number 076-21 on all slides. Slides for PT#1 and PT#2 had last names and first initials that were different, but had the same specimen number. 3. The handwritten Mohs map for PT#1 dated 7/14/2021 had the specimen number as MT#076-21 4. Mohs Log revealed the following : a.) PT#1 specimen number 075-21 b.) PT#2 specimen number 076-21 5. The "Progress Note" for PT#1 which included the Mohs Map listed the specimen number "Mohs #075-21" 6. The "Visit Note" for PT#1 listed the Mohs Case Number as "075-21". The visit note included the copy of the Mohs Map. 7. During interview on 1/25/2023 at 2:37 PM, SP-1 (Laboratory Director) confirmed the slides for PT#1 were labeled incorrectly.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based observation, record review and interview, the laboratory failed to document humidity for Avantik Cryostat (QS11/QS11UV) for 24(January 2021 to December 2022) of 24 months reviewed in 2021 and 2022. Findings Included: 1. During a tour of the MOHS Lab on 1/25/2023 at 10:33 AM, revealed a cryostat Avantik (QS11 /QS11UV) used for MOHS testing. 2. Review of "Technical Data QS11/QS11UV" stated "operating conditions + 5 Celsius(C) up to +35 C (at a max rel. humidity of 60%) 3. Review of "Daily Quality Control Log-Month/Year" from January 2021 to December 2022 indicated humidity was not documented. 4. During an interview on 1 /25/2023 at 2:37 PM, Sp-1 (Laboratory Director) confirmed that humidity was not recorded for the cryostat for 24 of 24 months reviewed in 2021 and 2022.