Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0858935	(X3) Date Survey Completed 01/16/2024
Name of Provider or Supplier Base Of The Bays Dermatology, Pc	**Street Address, City, State** 3950 Shore Road, Williamsburg, MI	

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
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 record review and interview with the Laboratory Director, the laboratory failed to verify the accuracy of its Mohs surgery tissue examination testing at least twice annually for 2 (2022 and 2023) of 2 years reviewed. Findings include: 1. A review of the laboratory's "American Society for Mohs Surgery Peer Review Results (ASMS)" revealed a lack of documentation for the verification of accuracy testing for Mohs surgery cases was not performed twice annually for 2 (2022 and 2023) of 2 years as follows: a. ASMS performed 4/24/2022 - no documentation for July-December 2022. b. ASMS performed 12/28/2023 - no documentation for January - June 2023. 2. An interview on 1/16/2024 at 12:15 pm, the Laboratory Director confirmed verification of accuracy testing was not performed twice annually. ***Repeat Deficiency from 3/02/2020 survey***
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by:

	. Based on record review and interview with the Laboratory Director, the laboratory failed to receive documentation from the processing site for the daily Hematoxylin and Eosin (H&E) stain quality for its histopathology dermatology tissue specimens for 3 (#11, #15, and #19) of 19 patient records reviewed. Findings include: 1. A review of the H&E stain quality documents received from the processing laboratory on 1/16 /2023 at 12:09 pm revealed a lack of documentation for 3 of 19 patient records reviewed as follows: a. Patient #11 performed on 6/1/2022 - no H&E stain quality documentation. b. Patient #15 performed on 4/11/2023 - no H&E stain quality documentation. c. Patient #19 performed on 12/5/2023 - no H&E stain quality documentation. 2. An interview on 1/16/2023 at 2:30 pm, the Laboratory Director confirmed the laboratory was missing the processing site H&E stain quality for the dates listed above.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: . . Based on record review and interview with the Laboratory Director, the laboratory failed to document time of histopathology Mohs tissue specimen receipt into the laboratory for 3 (Patients #2, #3, and #8) of 19 patient test records reviewed. Findings include: 1. A record review of patient Mohs' maps revealed a lack of documented time of specimen receipt into the laboratory for 3 (Patient #2, #3, and #8) of 19 patient records reviewed as follows: a. Patient #2 testing performed on 7/17/2022 - no stage II receipt time. b. Patient #3 testing performed on 9/17/2022 - no stage II receipt time. c. Patient #8 testing performed on 9/23/2023 - no stage II receipt time. 2. An interview on 1/16/2024 at 2:30 pm, the Laboratory Director confirmed the patients listed above did not have the time of specimen receipt into the laboratory documented for stage II.