Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2137582	02/06/2025
Name of Provider or Supplier	**Street Address, City, State**	
Dermatology Associates	13401 S Ridgeland Ave, Palos Heights, IL	

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 review of laboratory policies and procedures, review of laboratory records, lack of documentation, and interview with the laboratory representative, the laboratory failed to perform bi-annual method accuracy (proficiency testing/peer reviewed histopathology interpretations) at least twice annually for histopathology testing in the year of 2024. Findings include: 1. Review of laboratory policies and procedures revealed the procedure, "Quality Assurance Procedure of Histopathology Interpretation", which stated: a. Under "Procedure", "Twice a year, six randomly selected slides with common histopathological diagnoses, previously reviewed by [the LD], are sent to another physician after the initial diagnostic interpretation has been made." b. Under "Corrective Maintenance", "If staff fail to set up histopathology interpretation every 6 months, our lab director will review the procedure with them, emphasize the importance of conducting the required quality assurance check, and ensure consistent documentation is maintained." 2. Review of laboratory records, including that of bi-annual peer reviewed histopathology interpretations, revealed only one peer reviewed histopathology case was sent out in the year of 2024. Date: Case #: 10/11/2024 24-012 3. Interview with the laboratory representative on 02/06/2025, at 1: 42 pm, confirmed the laboratory failed to perform bi-annual method accuracy at least twice annually for histopathology testing in the year of 2024.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented.

	This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation, and interview with the laboratory representative, the laboratory failed to evaluate results of bi-annual method accuracy (proficiency testing/peer reviewed histopathology interpretations) for three of three events from the beginning of 2023 to the date of survey, 02/06/2025. Findings include: 1. Review of laboratory records revealed a lack of documentation of evaluations of results upon receipt of peer reviewed histopathology interpretations for three of three reviewed bi-annual method accuracy events. 2. Interview with the laboratory representative on 02/06/2025, at 1:42 pm, confirmed the laboratory failed to document evaluation of results of peer reviewed histopathology interpretations from the beginning of 2023 to the date of survey, 02/06/2025.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, review of laboratory records, lack of documentation, and interview with the laboratory representative, the laboratory failed to follow policies and procedures regarding bi-annual method accuracy (proficiency testing/peer reviewed histopathology interpretations) for one of three events from the beginning of 2023 to the date of survey, 02/06/2025. Findings include: 1. Review of laboratory policies and procedures revealed the procedure, "Quality Assurance Procedure of Histopathology Interpretation", which stated: a. Under "Procedure", "Twice a year, six randomly selected slides with common histopathological diagnoses, previously reviewed by Dr. Iyengar, are sent to another physician after the initial diagnostic interpretation has been made." b. Under "Corrective Maintenance", "If staff fail to set up histopathology interpretation every 6 months, our lab director will review the procedure with them, emphasize the importance of conducting the required quality assurance check, and ensure consistent documentation is maintained." 2. Review of laboratory records, including that of bi-annual peer reviewed histopathology interpretations, revealed only one peer reviewed histopathology case was sent out in the year of 2024. Date(s): # of Cases: January - June, 2023 Six July - December, 2023 Six October 11, 2024 One 3. Interview with the laboratory representative on 02/06/2025, at 1:42 pm, confirmed the laboratory failed to follow policies and procedures regarding bi-annual method accuracy (proficiency testing/peer reviewed histopathology interpretations) for one of three events from the beginning of 2023 to the date of survey, 02/06/2025.
D5805	TEST REPORT CFR(s): 493.1291(c) (c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test

	performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the laboratory representative, the laboratory failed to include the address of the laboratory that performed the histopathology testing for four of four Mohs surgical patient reports reviewed from the beginning of 2023 to the date of testing, 02/06/2025. Findings include: 1. Review of four of four Mohs surgical patient reports for histopathology testing found the laboratory failed to indicate the address of the performing laboratory on the final reports. Patient Accession #: Date of Testing: 146336 02/07/2023 117694 07/25/2023 121541 12/08/2023 174326 10/11/2024 2. Interview with the laboratory representative on 02/06/2025, at 1:13 pm, confirmed the laboratory failed to include the address of the laboratory that performed the histopathology testing for four of four Mohs surgical patient reports reviewed from the beginning of 2023 to the date of testing, 02/06/2025.
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) (e)(4)(iv) An approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory; This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, review of laboratory records, lack of documentation, and interview with the laboratory representative, the laboratory director failed to follow an approved corrective action plan for three of three bi-annual method accuracy (proficiency testing/peer reviewed histopathology interpretations) events from the beginning of 2023 to the date of survey, 02/06/2025. Findings include: 1. Review of laboratory policies and procedures revealed the procedure, "Quality Assurance Procedure of Histopathology Interpretation", which stated, under "Corrective Maintenance", "If staff fail to set up histopathology interpretation every 6 months, our lab director will review the procedure with them, emphasize the importance of conducting the required quality assurance check, and ensure consistent documentation is maintained." 2. Review of laboratory records revealed a lack of documentation of evaluations of results upon receipt of peer reviewed histopathology interpretations for three of three reviewed bi-annual method accuracy events. See D5221. 3. Interview with the laboratory representative on 02/06 /2025, at 1:42 pm, confirmed the laboratory director failed to follow an approved corrective action plan for bi-annual method accuracy (proficiency testing/peer reviewed histopathology interpretations) events from the beginning of 2023 to the date of survey, 02/06/2025.