Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D2080229	01/06/2023
Name of Provider or Supplier	**Street Address, City, State**	
Dermatology And Skin Surgery Center At, The	7200 Creedmoor Road, Suite 104, Raleigh, NC	

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 procedures, review of 2020, 2021 and 2022 laboratory records and interview with laboratory manager 1/6/23, the laboratory failed to verify the accuracy of the Mohs testing 10 months in 2020, 7 months in 2021 and 5 months of 2022. The laboratory also failed to verify the accuracy of the Mart-1 testing performed since testing began in March of 2020, a period of approximately 34 months. Findings: The laboratory began performing Mohs and Mart-1 testing under the current facility and laboratory director in March of 2020. Review of laboratory procedure "QUALITY ASSESSMENT PLAN" revealed "4. Proficiency Testing...A 30th case review of Mohs and Mart-1 Immuno cases are sent for peer review monthly.". Review of laboratory procedure "6. Proficiency Testing Policy... Procedure...A 30th case review of Mohs and Mart-1 Immuno cases are sent for peer review monthly.". Review of 2020, 2021 and 2022 laboratory records for Mohs proficiency testing (verification of accuracy) revealed a 30th case review of Mohs testing was performed in August, September, and October of 2021 and January, February, March, April, May and June of 2022. There was no documentation for Mohs testing verification of accuracy for the following months: 1. March, April, May, June, July, August, September, October, November, and December of 2020, a period of 10 months. 2. January, February, March, April, May, June, and July of 2021, a period of 7 months. 3. July, August, September, October, and November of 2022, a period of 5 months. Review of 2020, 2021, and 2022 laboratory records for Mart-1 proficiency testing (verification of accuracy) revealed no documentation of a verification of accuracy for the Mart-1 testing since testing began in March of 2020, a period of approximately 34 months. Interview with laboratory manager at

	approximately 12:00 p.m. confirmed testing began in March of 2020. She also confirmed verification of accuracy for the Mohs and Mart-1 testing was not performed as required. She stated she was hired in 2022 and has been working to ensure procedures and policies are maintained.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: Based on review of laboratory procedures, review of 2020, 2021 and 2022 laboratory records and interview with laboratory manager 1/6/23, the laboratory director failed to ensure the accuracy of the Mohs and Mart-1 testing performed. Findings: See D5217.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of laboratory procedure, review of testing personnel (TP) training and 2020, 2021 and 2022 competency records, and interview with laboratory manager 1/6/23, the technical supervisor (laboratory director) failed to ensure 2 of 2 TP had documented training and failed to ensure 2 of 2 TP had biannual competency assessments the first year of testing in 2020, and a yearly competency assessment in 2021. Findings: Review of laboratory procedure "QUALITY ASSESSMENT PLAN" revealed "3. Personnel Competency...This laboratory will ensure that all testing personnel are properly trained and are competent prior to testing patient specimens. Upon, hire, testing personnel will be required to perform and be deemed successful at each laboratory test they perform by the laboratory director, followed by a six month review. At least annually the laboratory director and/or technical consultant will review the performance of each employee working in the laboratory to assure employee competency.". Review of laboratory TP training records revealed no documentation of training for TP #2 and TP #3 who began testing in March of 2020. Review of laboratory TP competency records revealed no documentation of biannual competency assessment in 2020 for TP #2 and TP #3. Records also revealed no documentation of annual competency assessment in 2021 for TP #2 and TP #3. Interview with laboratory manager at approximately 10:45 a.m. confirmed training was not documented and also confirmed competency assessments were not performed as required for TP #2 and TP #3. She stated she did ensure TP competency was performed in 2022 when she began employment.