Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0243601	01/27/2022
Name of Provider or Supplier	**Street Address, City, State**	
Dermatology Group Of The Carolinas	525 Corporate Circle, Salisbury, 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
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. This STANDARD is not met as evidenced by: Based on review of laboratory procedure manual and review of laboratory maintenance procedure 1/27/22, the laboratory procedure manual failed to specify the corrective actions to perform when room temperature or humidity are out of range. Findings: Review of laboratory maintenance procedure revealed under section 3.0 "Maintenance...3.1.4 Record room temperature and humidity daily. 3.1.5 Document any activity and corrective action on the appropriate maintenance record form.". The procedure fails to specify the corrective actions to perform when room temperature or humidity are out of range. Review of laboratory procedure manual revealed no additional policy for corrective actions when room temperature or humidity are out of range.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the

	laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of cryostat operator's manual, review of laboratory procedure, review of 2019 and 2020 "Cryostat Preventative Maintenance" logs and interview with laboratory manager 1/27/22, the laboratory failed to document corrective action when room humidity was out of range. Findings: Review of cryostat operator's manual revealed humidity performance specifications of less than or equal to 60 percent (60%). Review of laboratory maintenance procedure revealed under section 3.0 "Maintenance...3.1.4 Record room temperature and humidity daily. 3.1.5 Document any activity and corrective action on the appropriate maintenance record form.". Review of 2019 and 2020 "Cryostat Preventative Maintenance" logs revealed corrective action was not documented for humidity ranges greater than 60% on the following dates when patient testing occurred. a. 4 of 7 days in July 2019 (9, 11, 16, 23). b. 7 of 9 days in August 2019 (6, 8, 13, 15, 20, 22, 27). c. 2 of 7 days in September 2019 (3, 17). d. 4 of 10 days in October 2019 (1, 3, 8, 31). e. 6 of 7 days in July 2020 (7, 9, 11, 23, 28, 30). f. 4 of 8 days in August 2020 (4, 6, 11, 13). g. 2 of 9 days in September 2020 (17, 29). h. 4 of 14 days October 2020 (1, 2, 5 and 8). Interview with laboratory manager at approximately 12:00 p.m. confirmed the laboratory failed to document corrective action when room humidity was greater than 60%.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of laboratory quality assessment (QA) policies, review of 2019 and 2020 "Quality Control Review" forms, deficiency cited at D5781 and interview with laboratory manager 1/27/22, the laboratory's QA policies failed to identify out of range room humidity in 2019 and 2020. Findings: Review of laboratory QA policies revealed a "Quality Control Review" form which consists of a monthly checklist that monitors laboratory functions. For example: "Daily H&E control slide (Review data monthly)" and "Stain/Reagent Log" (Review data monthly)". Review of 2019 and 2020 "Quality Control Review" forms revealed for July, August, September, and October of 2019 and 2020 the monthly monitor of the laboratory function "Cryostat PM log" was initialed as reviewed. The review failed to identify out of range room humidity cited at time of survey. See D5781. Interview with laboratory manager at approximate 1:30 p.m. confirmed the "Cryostat PM log" was initialed as reviewed and failed to identify our of range room humidity.