Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D2320011	06/05/2026
Name of Provider or Supplier	**Street Address, City, State**	
Carolina Skin Institute, Pa	89 Hospital Drive, Suite A-Up1, Brevard, 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
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the Quality Assurance Program policy, absence of performance specification verification records, and interview with the Histotech on 6/5/26, the laboratory failed to validate performance specifications for new test methodologies prior to patient testing, including Hematoxylin and Eosin (H&E) staining methods performed manually and automated on the HistoPro 414 Linear Stainer. Findings: 1. Review of page 3 of the Quality Assurance Program policy revealed a section titled, "Verification of Method Performance Specifications." This section explained, "The laboratory will establish performance specifications for any new test methodology... based on Accuracy, Precision, Analytical sensitivity, Analytical specificity...., Reportable range..., and Any other performance characteristic required to test performance." This section also explained, "The laboratory will document verification of applicable test performance specifications and will maintain the documentation for the life of the methodology...." 2. Review of quality and maintenance records for the manual and automated H&E staining methodologies revealed the absence of performance specification verification records. 3. During an interview at approximately 11:30 a.m., the Histotech confirmed there were no performance specification verification records available for the staining methodologies and studies were not performed and documented at the laboratory prior to use for patient testing.

D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and This STANDARD is not met as evidenced by: Based on the absence of performance specification verification records, review of the Quality Assurance Program policy, and interview with the Laboratory Director (LD) on 6/5/26, the Laboratory Director failed to ensure adequate verification of performance specifications for test methodologies used in the laboratory. Findings: 1. Review of quality and maintenance records for the manual and automated Hematoxylin and Eosin (H&E) staining methods revealed the absence of performance specification verification records. 2. Review of page 2 of the Quality Assurance Program policy revealed a section titled, "Test Methods, Equipment, Reagents, Materials and Supplies." This section explained, "The Laboratory Director will ensure that proper test validations have been performed on all tests performed in the laboratory before reporting any patient test results." 3. During an interview at approximately 1:50 p.m., the LD confirmed that the performance specifications for the manual and automated H&E staining methods were not validated prior to patient testing as stated on page 3 of the Quality Assurance Program policy. See D5421.