Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	42D0249423	06/18/2025
Name of Provider or Supplier	**Street Address, City, State**	
Columbia Skin Clinic Llc	3600 Forest Drive, Suite 400, Columbia, SC	

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
D0000	An onsite CLIA recertification survey was conducted at Columbia Skin Clinic, LLC on June 18, 2025. The facility was found to be out of compliance with the Medicare Condition at 42 CFR 493 Laboratory Requirements. The following is a list of STANDARD LEVEL deficiencies cited as a result of June 18, 2025, recertification survey.
D3013	FACILITIES CFR(s): 493.1101(e) Records and, as applicable, slides, blocks, and tissues must be maintained and stored under conditions that ensure proper preservation. This STANDARD is not met as evidenced by: Based on direct observation, lack of documentation and staff interview, the laboratory failed to monitor temperature and humidity for the room histology slides and paraffin blocks were kept as required for facilities 493.1101 to maintain and store under conditions that ensure proper preservation. Findings included: 1. A tour of the storage room on June 18, 2025, at 1:30 pm, the surveyor observed: a. In a room next to breakroom and the conference area, histology slides and paraffin blocks from 2014 thru 2025. b. No devices to monitor temperature and humidity in the room on day of survey. 2. Surveyor requested and laboratory failed to provide, documentation of temperature and humidity for the room storing slides and blocks processed by the histology laboratory. 3. In an interview on June 18, 2025, at 6:35 pm with testing personnel, and laboratory director (LD) in the conference room, the above findings were confirmed.
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, lack of documentation, and staff interview, the laboratory failed to verify the accuracy of the test or procedure twice annually for provider performed microscopy (PPM) test. Findings included: 1. A review of CMS 116 reveals the laboratory performs and reports potassium hydroxide (KOH) subspecialty mycology. 2. A review of records reveals the laboratory failed to document twice annually provider performed microscopy test. 3. The surveyor requested but the laboratory failed to provide accuracy of test or documentation of a procedure used twice annually or any other method used for proficiency testing of mycology on June 18, 2025, at 6:35 pm in an interview with testing personnel and laboratory director in the breakroom.
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 direct observation, records review and staff interview, the laboratory lacked documentation of verification of performance specifications as required 493.1253 for each nonwaived unmodified FDA cleared or approved test system before reporting patient(s) test results. Findings included: 1. A tour of the laboratory on June 18, 2025, at 4:35 pm the surveyor directly observed three Thermo Scientific Microtome HM 550. 2. Records review reveals, the laboratory lacked documentation of performance specifications for new equipment. 3. In an interview on June 18, 2025, at 6:35 pm with testing personnel and laboratory director in the breakroom the above findings were confirmed.
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. This STANDARD is not met as evidenced by: Based on review of patient reports, and staff interview the laboratory failed to document the positive and negative reactivity for special stains as required 493.1273 for 2 out of 2 random patients reviewed. Finding included: 1. During a review of patient's records on June 18, 2025, at 5:00 pm, the surveyor observed that special

	stains were reported on patients results: a. Patient, Acession#D24-14202, under microscopic description, a PAS stain for fungi was performed, and there was no documentation of acceptable positive and negative reactivity for controls. b. Patient, Acession#D25-06846, under microscopic description, a PAS stain for fungi was performed, and there was no documentation of acceptable positive and negative reactivity for controls. 2. Surveyor requested and laboratory failed to provide, documentation of positive and negative control reactivity. 3. In an interview on June 18, 2025, at 6:35 pm with testing personnel and laboratory director in the breakroom the above findings were confirmed.