Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 42D2261774	(X3) Date Survey Completed 06/19/2024
Name of Provider or Supplier Columbia Skin Clinic, Llc	**Street Address, City, State** 7039 St Andrews Road, 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 on-site announced CLIA initial compliance survey was conducted at the MOHS Laboratory, Columbia Skin Clinic LLC by the South Carolina Department of Health and Environmental Control's (SC DHEC) Bureau of Healthcare Systems and Services on June 19, 2024. The laboratory was found to be out of compliance with 42 CFR Part 493, CLIA Requirements for Laboratories. The following is a description of the standard level deficiencies:
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on lack of documentation and staff interview, the laboratory failed to ensure competency assessments for personnel listed on the CMS-209 form. Findings inlcuded : 1. No competency assessments for the Laboratory Director (LD), Clinical Consultant (CC), and Technical Superevisor (TS). 2. No competency assessments for Testing Personnel (TP) as the General Supervisor (GS) 3. In an interview with the TP in the laboratory on June 19, 2024 at 11:00 am, the findings were confirmed.
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.

	This STANDARD is not met as evidenced by: Based on record review, policy review and staff interview, the laboratory failed to ensure the bi-annual accuracy assessments for diagnosis. Findings included: 1. The laboratory's Quality Assessment Policy states "Four cases every quarter are randomly selected and submitted to the in-house board certified dermatopathologist.." For 2024, only one peer review submission was available dated 5/7/2024. 2. Quarterly peer review meets the CLIA quality assesment standard, however documentation of quarterly review was not available. 3. In an interview with TP on June 19, 2024 at 11: 00 am in the laboratory, findings were confirmed.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on lack of documentation and staff interview, the LD failed to ensure documentation of personnel competencies for 2 of 2 employees listed on the CMS-209 form. Findings included: 1. No documentation of competency assessments were available for the LD in her role as the LD,CC, and TS. 2. No documentation of competency assessments were available for the TP in her role as the GS. 3. In an interview with the TP on June 19, 2024 at 11:00 am in the laboratory, findings were confirmed.