Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	42D2108841	09/17/2024
Name of Provider or Supplier	**Street Address, City, State**	
Aiken Dermatopathology Annex	1520 Two Notch Rd, Se, Aiken, 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 announced CLIA recertification survey was conducted on September 17, 2024, at the clinical laboratory of Aiken Dermatopathology Annex by the South Carolina Departrment of Public Health's Bureau of Nursing Homes and Medical Services. 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 defiociencies cited:
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on laboratory document review and staff interview, the laboratory failed to have a written policy and procedure to monitor twice annual accuracy assessments. Findings included: 1. Review of laboratory policy and procedures reveals a lack of a written procedure for twice annual quality assessments. 2. Review of laboratory records reveals a lack of documentation for twice annual accuracy assessments. 3. Review of laboratory records reveals a lack of documentation for peer review for accuracy of tissue diagnosis. 4. In an interview on September 17, 2024, at 11:30am in the laboratory's mircoscope room with the Laboratory Director, the findings were confirmed.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on laboratory policy and procedure review, laboratory documentation review, and staff interview, the Laboratory Director failed to ensure the quality assessment programs are established and maintained to assure the quality of laboratory services provided. Finding included: 1. Review of laboratory policy and procedures reveals a lack of a written procedure for twice annual quality assessments. 2. Review of laboratory records reveals a lack of documentation for twice annual accuracy assessments. 3. Review of laboratory records reveals a lack of documentation of peer review for accuracy of tissue diagnosis. 4. In an interview on September 17, 2024, at 11:30am in the laboratory's mircoscope room with the Laboratory Director, the findings were confirmed.