Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D1020334	01/25/2024
Name of Provider or Supplier	**Street Address, City, State**	
Kayal Dermatology And Skin Cancer	141 Lacy Street, Suite 200, Marietta, GA	

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	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on January 25, 2024. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
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 Quality Assessment (QA) document review and staff interview, the laboratory failed to document quality assessment activities on a monthly basis as stated in their QA policy manual in 2022 and 2023. Findings: 1. A review of the laboratory QA documents revealed the technical supervisor (TS) did not review and sign monthly quality activity checklists from May 2022 thru December 2023 in the Specialty of Histopathology. 2. A review of daily maintenance logs including: Room Temperature, Humidity, Cryostat, Eye Wash and Refrigerator logs were not reviewed and signed by the Laboratory Director (LD) or General Supervisor (GS) from May 2022 thru December 2023. 3. Interviews with the GS (TP#2 CMS 209) and office manager on 01/25/2024, at approximately 12:35 pm in the review room confirmed the above laboratory logs and QA checklists were not reviewed and signed by the GS or LD from May 2022 thru December 2023.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8)

	(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on record review and interview with the technical supervisor, the laboratory failed to ensure the performance of training, semi-annual and annual competency assessments were completed for testing personnel (TPs) performing Potassium Hydroxide (PPM - KOH) testing in 2022 and 2023. Finding: 1. A review of laboratory training and competency records failed to identify the training/competency assessments for Provider Performance Microscopy (PPM) (KOH) prep for skin fungal identification for (TPs #s 3 - 6 CMS 209) in 2022 or 2023. 2.There was no peer review performed twice annually or proficiency testing (PT) from a CMS approved agency to test the competency of PPM testing personnel. 3. An interview with the General Supervisor (GS) and office manager, in the review room, at approximately 1: 00 PM, on 01/25/2024 confirmed the abscence of training records and competencies for (TPs #s 3 - 6 CMS 209) in 2022 or 2023.