Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	38D1004676	01/16/2025
Name of Provider or Supplier	**Street Address, City, State**	
Klein Dermatology And Associates	5200 Sw Meadows Rd Ste 250, Lake Oswego, OR	

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
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 review of the procedure manual during survey, the procedure developed by the laboratory after the March 1st, 2021 CLIA survey and interview with RN #1, the laboratory failed to ensure at least twice annual verification of accuracy for the slides read digitally at this office. Findings include: 1. Upon review of the procedures in the procedure manual presented for review during this survey, a current and approved procedure for processing and interpretation of biopsied tissue specimens, including collection, processing, reading of slides and verification of accuracy, could not be produced. 2. I allowed the laboratory four (4) days to produce the procedure, due to a recent change in personnel responsible for maintaining records. 3. On January 21, 2025, the laboratory (RN #1) submitted a procedure titled "Dermatopathology Policies and Procedures", signed by the Laboratory Director on March 21, 2021. Number eighteen (18) in this procedure states: "18. Quality Assurance: The physician attends regular CME meetings that include dermatopathology, and their maintenance of certification (MOC) also includes testing on dermatopathology. In addition, five cases per quarter will be double read for quality assurance, meaning our physician will read the slide and create a pathology report, and also have CTA read the slide and create a pathology report to confirm that there is agreement in the diagnosis. These cases will be highlighted in pink in the pathology book". 4. Request for records of quarterly slide interpretation accuracy verification, per the procedure submited January 21, 2025, for histopathology slides read digitally, revealed that the last record of slide interpretation /verification of accuracy from an outside lab was March 25, 2021. 5. The laboratory failed to ensure that quarterly verification of accuracy, per their policy and procedure, was followed. Accuracy verification has not been performed since 03/25/2021. 6. The

	laboratory reports a volume of 1160 histopathology slides read annually. 7. RN #1 confirmed these findings during interview at 12:30 pm during survey and by phone on January 17th, 2025 at 11:58 a.m.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of the policies and procedures for the collection, processing, interpretation and peer review of histopathology slides read at this site, the laboratory failed to follow their written and approved policy. Findings include: 1. The laboratory failed to ensure that a current and approved procedure was available to all individuals involved in the collection and processing of tissue biopsies retrieved at this lab. 2. See D5217