Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D1104449	09/23/2025
Name of Provider or Supplier	**Street Address, City, State**	
Kinnelon Dermatology Associates	135 Kinnelon Road Suite 103, Kinnelon, NJ	

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 surveyor review of the Biannual Assessments (BA) records and interview with the Histotechnician (HT), the laboratory failed to verify the accuracy of Histopathology testing biannually from 12/16/24 to 9/23/25. The findings include: 1. Surveyor review of the BA records revealed the laboratory had incomplete BA records for the following cases: a) Case # 24-335 reviewed by the Laboratory Director (LD) on 12/18/24 b) Case # 24-68 reviewed by the LD on 5/15/24 c) Case # 24-121 reviewed by the LD on 5/15/24 2. The HT confirmed on 9/23/25 at 1:30 pm, the laboratory did not verify the accuracy of Histopathology testing biannually.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) (d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), observation of the staining station and interview with the Histotechnician (HT), the laboratory failed to have staining procedures approved by the Laboratory Director (LD) from 2/15/24 to 9/23 /25. The finding includes: 1. The laboratory had two different Hematoxylin and Eosin (HE) staining procedures located in the PM and above the staining station. 2. Interview with the HT revealed the laboratory is using the staining procedure above

	the staining station and not the procedure in the PM. 3. There were no implementation or discontinuance dates on the HE procedures. 4. The HT confirmed on 9/23/25 at 1: 20 pm the laboratory did not have implementation or discontinuance dates on the HE procedures approved by the LD.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) (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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), lack of Quality Assurance Electronic Medical Records (QAEMR) Map Logs and interview with the Histotechnician (HT), the laboratory failed to follow their procedure in the postanalytic systems for "Quality Assurance" from 2/15/24 to 9/23/25. The finding includes: 1. The PM stated "Every January and July EMR maps from the Biannual Assessment cases should be checked to make sure they were scanned and put into the patients chart. The findings and corrective action taken if necessary will be noted on the QA EMR Map Log." 2. There were no QA EMR Map Logs available for review. 3. The HT confirmed on 9/23/25 at 1:45pm, the laboratory did not follow their procedure in the postanalytic systems.