

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D1104449	(X3) Date Survey Completed 10/10/2023
Name of Provider or Supplier Kinnelon Dermatology Associates	Street Address, City, State 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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on survey review of the Procedure Manual (PM), Biannual Assessment (BA) records and interview with the Office Manager (OM) the laboratory failed to follow procedures for Biannual Assessment for Histopathology testing in the calendar years of 2022 and 2023. The findings include: 1. The PM states " Evaluation and review will be documented by the laboratory director on the BA form. If they do not agree then the slides will be sent to a third party." 2. The BA case # 22-275 shows non agreement for Slide # 12. There was no documented evidence the slides were sent to a third party for review. 3. There was no documented evidence that the Laboratory Director (LD) evaluated and reviewed the BA performed for 2 out of 2 events for 2022 and 1 out of 2 events for 2023. 4. The reviewing pathologist for BA events of 2022 and 2023 is not listed as a reviewing pathologist on the BA procedure. 5. The laboratory failed to have the credentials of the reviewing pathologist at the time of survey. 6. The OM confirmed on 10/10/23 at 11:00 am that the laboratory failed to follow procedures for BA for Histopathology.</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p>

This STANDARD is not met as evidenced by:
Based on surveyor observation of Histopathology reagents, the Flammable Cabinet, and interview with the Office Manager (OM), the laboratory used and failed to dispose expired Histopathology reagents and dyes from 7/1/2020 to the date of survey. The findings include: 1. The Procedure Manual (PM) states " the expiration date is to be circled and the reagent is to be disposed of when the expiration date is reached." The following reagents were observed to be expired. a. one violet tissue marking dye lot 082181 expired on 7/1/2020. b. one black tissue marking dye lot 085357 expired on 8/31/21. c. one green tissue marking dye lot 085405 expired on 8/31/21. d. one orange tissue marking dye lot 085400 expired on 8/31/21. e. two Submount 4oz. Mounting Media lot 1145 expired on 5/25/22. f. one CoverMount 4oz. lot 107975 expired on 10/31/22. g. one 95% Reagent Alcohol 1 gallon container lot 125677 expired on 7/31/23. 2. The laboratory performed approximately 500 Histopathology tests annually. 3. The OM confirmed on 10/10/23 at 10:30 am that the laboratory used and failed to dispose the expired reagents and dyes.

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 surveyor review of the Procedure Manual, a lack of a Reagent Tracking Log and interview with the Office Manager (OM) the laboratory failed to establish policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic system from 6/25/19 to the date of survey. The finding includes: 1. The laboratory failed to have a procedure for tracking reagents and dyes used in Histopathology testing. 2. The OM confirmed on 10/10/23 at 11:15 am that the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems.