Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2035208	09/08/2021
Name of Provider or Supplier	**Street Address, City, State**	
Haddonfield Dermatology Associates	24 West Kings Highway, Haddonfield, 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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on surveyor review of the Competency Assessment (CA) records and interview with the Office Manager (OM) the laboratory failed to follow its policies and procedures for assessing the competency of Testing Personnel who perform Histopathology testing in the calendar year 2020. The findings include: 1. The CA was not performed on one out of one TP in 2020. 2. The OM confirmed on 9/8/21 at 2: 00 pm that the CA was not performed.
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 Assessment (BA) records and interview with the Office Manager (OM), the laboratory failed to verify the accuracy of Histopathology testing in the calendar 2021. The finding includes: 1) Biannual assement has not been performed since June 2020. 2) The OM confirmed on 9/8/21 at 1:00 pm that the laboratory did not perform BA for Histopathology since June 2020.
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 surveyor review of the Procedure Manual and interview with the Office Manager (OM), the laboratory failed to establish a detailed procedure for Biannual Assessment (BA) from 4/12/18 to the date of survey. The finding includes: 1. The BA procedure did not include the name of the referring pathologist. 2. The OM confirmed on 9/8/21 at 2:15 pm that the BA procedure was not in detail.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) 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. This STANDARD is not met as evidenced by: Based on surveyor observation of Histology reagents and interview with the Office Manager (OM), the laboratory failed to discard expired Histopathology reagents from 3/1/21 to the date of survey. The findings include: 1. On the date of the survey the laboratory used expired reagents as follows: a. Advantik Tissue marking dye red Lot 11-9002-12 expiration 3/1/21. b. Advantik Tissue marking dye yellow Lot: 11-9004-12 expiration 8/31//21. 2. The OM confirmed on 9/8/2021 at 1:30 pm that the laboratory used expired reagents.