Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	08D0936013	01/12/2022
Name of Provider or Supplier	**Street Address, City, State**	
Cape Henlopen Dermatology, Pa	750 Kings Highway Suite 110, Lewes, DE	

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 Recertification Survey was conducted at approximately 9:30 am on January 12, 2022 at Cape Henlopen and Nanicoke Dermatology, PA. The laboratory was surveyed according to 42 CFR part 493 CLIA requirements. Specific deficiencies are as follows:
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 lack of documentation and interview the laboratory failed to establish written policies and procedures to monitor or assess problems in the laboratory. Findings include: 1.At approximately 10:30 am on January 12, 2022 during record review, it was determined that there was no Standard Operating Procedure (SOP) or other documentation that identified a mechanism for performing ongoing general laboratory quality assessment to monitor, assess, or identify problems or potential problems. 2. At approximate 10:40 am documentation of quality systems assessment was requested by the surveyor. The laboratory was unable to provide the requested documentation. 3. During the interview at approximately 10:20 am, TP3 confirmed that there was no Systems Quality Assessment in place. The laboratory did not provide the record by the end of the survey at approximate 11:00 am.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper

	storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: based on lack of documentation, and interview of TP3 that the laboratory failed to document ranges for temperature and humidity to ensure manufacturer's storage requirements, and specimen integrity of patient slides. The findings include: 1. At approximately 10:40 am on January 12 2022, during document review it was determined that there was no documentation of room temperature or humidity in the lab where reagents and slides are stored. 2. Documentation of room temperature and humidity were requested at 10:45 but the laboratory was unable to provide requested documentation. 3. During the interview at approximately 11:00 am, TP3 confirmed lack of documentation for temperature and humidity. The laboratory did not provide the record by the end of the survey at approximately 11:00 am.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: based on record review and interview. The laboratory failed to address two of six elements of a competency assessment program in their Standard Operating Procedure (SOP). Findings include: 1. At approximately 10:30 am on January 11, 2020 during record review it was determined the Competency of Personnel Procedure included four required elements of competency assessment: "Direct observations of routine patient testing including patient preparation, specimen handling, processing and testing; Monitoring the recording and reporting of test results; Review of quality control records, proficiency testing results, and preventive maintenance records: Assessment of problem solving/troubleshooting skills". However, "Direct observations of performance of instrument maintenance and function checks", and "Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples" were not addressed in the SOP. 3. TC2 confirmed in an interview at approximately 10:40 am, that the competency assessment SOP did not address "Direct observations of performance of performance of instrument maintenance and function checks", and "Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples".