Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	08D2128804	09/07/2022
Name of Provider or Supplier	**Street Address, City, State**	
Burke Dermatology	353 Savannah Road, 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 12:00 pm on September 7, 2022 at Burke Dermatology, Lewes, Delaware. The Laboratory was surveyed according to 42 CFR part 493 CLIA requirements. Specific deficiencies are as follows:
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: lack of documentation, and interview the laboratory failed to provide documentation of Proficiency Testing (PT) as required. Findings include: 1. During documentation review at approximately 12:25 pmon September 7, 2022, no evidence of PT was provided for 2021 or 2022 for 3 of 3 personnel. 2. During the interview, the PM stated that the clinic is "in transition" and that records could be "at the Dover office". 3. By the end of the interview at approximately 1:10 pm, when PT documentation was again requested, no PT documents were provided for 2021 or 2022 for any personnel.
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:

	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 12:43 pm on September 7, 2022 during record review, it was determined 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. During interview at approximately 12:43 pm documentation of quality systems assessment was requested by the surveyor. The laboratory was unable to provide the requested documentation. The PM stated that the laboratory was "in transition" and documents may be "at the Dover office". 3. By the end of the survey at approximately 1:10 pm, no record of Systems Quality Assessment was provided when requested.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) 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. This STANDARD is not met as evidenced by: lack of documentation, and during interview, the laboratory failed to provide a written procedures manual for any activities performed by laboratory personnel. Findings include: 1. At approximately 12:37pm on September 7, 2022 during document review, no Standard Operating Procedure (SOP) was found for any activity performed by laboratory personnel. The only SOP available was titled "Burke Dermatology Proposed MOHS Protocol". It did not include specific step by step performance of any procedure but listed procedures that were appropriate for MOHS. 2. During the interview at approximately 12:37 pm, the PM stated the laboratory was "in transition" and documents and procedures could be "at the Dover office". 3. By the end of the interview at approximately 1:10 pm, SOPs were again requested, but none was provided for any laboratory testing or procedures.
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: observation, and interview the laboratory was using reagents that were beyond their expiration date. Findings include: 1. At approximately 12:16 pm on September 7, 2022 expired reagents were observed in the laboratory. In the storage cabinet, 2 of 6 reagents were expired: Gill 3 Hemotoxylin Lot 103484 expired on "2022-02-88" and Citra-Clear Xylene Substitute Lot 093134 expired on "2022-01-20". 2. During interview at approximately 12:16 pm, the TP stated that the "Hematoxylin bottle is waste", but there was no marking or label to indicate the contents or bottle as waste. 3. At the end of the survey at approximately 1:10 pm, the PM confirmed that the Citra-Clear was expired.

D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: by lack of documentation, and interview the laboratory failed to have qualified personnel assigned as the Testing Personnel (TP). Findings include: 1. During document review of new personnel qualifications at approximately 12:20 pm on September 7, 2022, no training or education documentation was provided for the Testing Personnel (TP) who was introduced as the "Histotech". 2. During the interview with the PM and the TP at approximately 12:20 pm, the PM pointed out that the CMS 209 does not state the TP is qualified as High Complexity. That box was left blank for the TP, while 3 of 3 other personnel were noted as directing or perfomring High Complexity testing. The PM stated that some documentation is maintained at the "other office" and that she would be going there the next day. She stated the laboratory was "in transition". 3. At the end of the interview at approximately 1:10 pm, training and education documents were requested a second time for the TP, but none was provided.