Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2165559	07/09/2024
Name of Provider or Supplier	**Street Address, City, State**	
Boswell Dermatology	6730 N West Avenue, Fresno, CA	

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
D3043	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(7) The laboratory must retain cytology slide preparations for at least 5 years from the date of examination (see 493.1274(f) for proficiency testing exception). The laboratory must retain histopathology slides for at least 10 years from the date of examination. The laboratory must retain pathology specimen blocks for at least 2 years from the date of examination. The laboratory must preserve remnants of tissue for pathology examination until a diagnosis is made on the specimen. This STANDARD is not met as evidenced by: Based on the lack of written policies and procedures manual for retention and storage applicable to dermatopathology, review of five (5) randomly chosen Mohs patient test records, and interviews with the office manager (OM) and histology technicians (HTs); the laboratory failed to have written policies for documentation and slide retention and storage for dermatopathology. The findings included: 1. Based on the survey on July 9, 2024, at approximately 10:00 a.m., no written policies for retention and storage of documents and slides were found at the time of survey. 2. The OM and HTs affirmed by interview on July 9, 2024, at approximately 10:00 a.m. that the laboratory had no retention and storage policies for documents and slides. 3. Based on the laboratory declaration form submitted on July 9, 2024, and review of 5 randomly chosen dermatopathology test records out of 2,050 tests performed annually for dermatopathology, the laboratory had no retention and storage policies.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3)

	Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on the surveyor's observation during the laboratory tour and interviews with the histology technicians (HTs), the laboratory failed to label reagents and solutions including preparation and expiration dates in various sections of the laboratory. The findings included: 1. Based on the surveyor's observation during the laboratory's tour on July 9, 2024, at approximately 12:30 p.m..; during processing of specimens, blocks and slides, no label identifying the ethanol staining jar on the cryostat was found as well as all the staining jars in the staining area had no identifying label, preparation, strength or concentration, and expiry dates for 100% ethanol, 95% ethanol, xylene, eosin, water, etc. 2. Based on the surveyor's observation during the laboratory's tour on July 9, 2024, all 10% KOH bottles found in every exam room with Lot#2090 had expired since 3-31-2024. 3. Both HTs affirmed in an interview conducted on July 9, 2024, at approximately 12:30 p.m. that the reagents and solutions mentioned in statements #1 and #2 were not properly labeled for any information such as identity, preparation and expiration dates, lot number, and other important information required for proper use. 4. Based on the laboratory's annual testing declaration submitted at the time of the survey, the laboratory analyzed approximately 2,421 test samples for Mycology, Parasitology and Histopathology.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. This STANDARD is not met as evidenced by: Based on the surveyor's observation during the laboratory's tour, review of the laboratory's records, review of thirteen randomly selected patient test results, and interviews with the laboratory's office manager and histology technicians on July 9, 2024; it was determined that the laboratory director is cited herein due to failure to ensure that several aspects of the preanalytic, analytic, and postanalytic phases of the laboratory testing were monitored. See D3043 and D5415.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must 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 the interviews with the office manager and histology technicians,

	competency, and policies and procedures record review on July 9, 2024, the laboratory director is herein cited for failure to ensure that established policies and procedures were not followed 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.