Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0295356	02/27/2020
Name of Provider or Supplier	**Street Address, City, State**	
Bliss Dermatology	699 S Indiana Avenue, Englewood, FL	

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	An announced CLIA recertification survey was conducted at Pennie Dermatology & Skin Surgery Center LLC on 02/27/2020. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on observation and interview with the Certified Registered Medical Assistant (CRMA) the laboratory failed to dispose of chemicals per the manufacturers' instructions for 2 (2018-2020) out of 2 years reviewed. Findings Included: During a tour of the laboratory on 02/27/2020 at 10:15 AM the following chemicals were observed: Xylene Substitute, Eosin Y Stain Solution, and 100% Reagent Alcohol. On each of the bottles it stated to dispose of contents/container to an approved waste disposal plant. Interview on 02/27/2020 at 10:15 AM with the CRMA revealed the chemicals were disposed of down the drain and not to an approved waste disposal plant.
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 record review and interview with the Certified Registered Medical Assistant (CRMA) the laboratory failed to verify the accuracy in Histopathology at least twice a year for 1 (2019) out of 2 years reviewed (2018-2020). Findings Included: Review of the "Proficiency Testing" procedure, updated 11/30/2016, revealed that "Semi-annually, the tech or medical assistant will send two cases containing the original slides, label it with only the surgical case number, and send it our for a microscopic examination by a Board Certified Dermatopathologist." Review of the Quality Assurance (QA) peer reviews for Histopathology revealed that in 2019 it was only verified 10/08/19. On 02/27/2020 at 10:14 AM, the CRMA confirmed that the QA peer review only occurred once in 2019.
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 observation, record review, and interview with the Certified Registered Medical Assistant (CRMA) the laboratory failed to ensure the Potassium Hydroxide (KOH) was not expired prior to patient testing since 02/27/2019. Findings Included: Observations taken while on tour on 02/27/2020 at 10:30 AM revealed KOH that expired on 02/27/2019. Review of Patient logs revealed that KOH testing was performed with the expired KOH on 10/03/2019 and 01/09/2020. Interview on 02/27 /2020 at 10:30 AM with the CRMA confirmed that the KOH was expired and that there was no other KOH available for use.