Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2116895	02/03/2022
Name of Provider or Supplier	**Street Address, City, State**	
Sun Dermatology	643 N Highway 231, Panama City, 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 recertification survey was conducted on February 3, 2022. Sun Dermatology clinical laboratory was not in compliance with 42 CFR 493, Requirements for Laboratories.
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 lab staff #A, the laboratory failed to verify the accuracy of wet mounts for Scabies and Potassium Hydroxide (KOH) at least twice annually for 2 of 2 (2020 and 2021) years reviewed. The findings included: Record review revealed only one KOH/Scabies Prep Sheet in 2020 dated 10/28/2020. The document was for KOH testing only. The Consult line was incomplete and the second signature was the original provider's signature, not a consulting provider. The KOH/Scabies Prep Sheet dated 1/20/2021 was for KOH testing only. The Consult line was incomplete and the second signature was the original provider's signature, not a consulting provider. The KOH/Scabies Prep Sheet dated 7/7//2021 was for KOH and Scabies testing. The Consult line was incomplete and the second signature was the original provider's signature, not a consulting provider. During an interview with lab staff #A on 2/03/2022 at approximately 1415, lab staff #A confirmed that wet mounts and KOH preps were not verified for accuracy at least twice annually.
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 record review and interview with lab staff #A, the laboratory failed to establish and document acceptable reference ranges for laboratory humidity, laboratory temperature, 3050 Leica Cryostat temperature, and 1850 Leica Cryostat temperature for 2 of 2 (2020 - 2021) years reviewed and January of 2022. Findings included: Record review of temperature and humidity logs discovered that the reference ranges were missing from the log sheets for: 1. Laboratory humidity and room temperature for all of 2020, 2021, and January of 2022 2. 3050 Leica Cryostat temperature for all of 2021 and January of 2022 3. 1850 Leica Cryostat temperature for January of 2022 Interview with lab staff #A at 1415 on February 3, 2022, confirmed the reference ranges for humidity and temperatures were not established and documented.
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 and interview with lab staff #A, the laboratory failed to have an in-date working bottle of Potassium Hydroxide (KOH). The findings include: During the lab tour on 2/03/2022, it was observed that the KOH reagent bottle in use (lot #K15213) was expired on February 2018. During interview on 2/03/2022 at 1415 with lab staff #A, it was confirmed that the KOH reagent bottle was dated to expire February of 2018. It was revealed that thirteen (13) patients had KOH testing done from 7/27/2018 through 10/14/2021.