Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D2142889	03/29/2021
Name of Provider or Supplier	**Street Address, City, State**	
Treasure Valley Dermatology & Skin Cancer Center	2535 E Fairview Ave, Meridian, ID	

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
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 of biannual verification documentation and an interview with the laboratory technician on 03/29/2021, the laboratory failed to document the verification of accuracy for potassium hydroxide (KOH) examinations, at least twice annually. The findings include: 1. A record review of biannual verification documentation on 03/29/2021 revealed that the laboratory failed to document the verification of accuracy for KOH examinations, at least twice annually, since the last survey on 03/04/2019. 2. An interview with the laboratory technician on 03/29/2021 at 1:40 PM confirmed that the laboratory failed to document verification of accuracy for KOH examinations. 3. The laboratory reports performing 20 KOH examinations annually. 4. This is a repeat deficiency from the previous survey on 03/04/2019.
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 a record review of the laboratory's temperature logs, Avantik QS12 Cryostat Instruction Manual, and an interview with the laboratory technician on 03/29/2021, the laboratory failed to monitor and document room temperature in the laboratory for acceptable temperature ranges. The findings include: 1. A record review of the laboratory's cryostat log sheets revealed that the laboratory failed to document that room temperature was being monitored each day of patient testing when operating the Avantik QS12 Cryostat. 2. A record review of the Avantik QS12 Cryostat Manual, page 12, indicated the environmental temperature operating limits of +5C to +35C, in which the laboratory failed to monitor and document. 3. An interview with the laboratory technician on 03/29/2021 at 2:10 PM confirmed that room temperature, where the cryostat is located has never been documented. 4. The laboratory reports performing 275 Moh's slide examinations annually.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on record review of the laboratory's maintenance logs, Avantik QS12 Cryostat Instruction Manual, and an interview with the laboratory technician on 03/29/2021, the laboratory failed to follow the Avantik QS12 Cryostat Instruction Manual and perform maintenance as specified by the manufacturer. The findings include: 1. A record review of the laboratory's maintenance logs revealed that the laboratory failed to document performing maintenance as specified by the manufacturer on pages 53-54 of the Avantik QS12 Cryostat Instruction Manual. 2. An interview with the laboratory technician on 03/29/2021 at 2:10 PM confirmed that the laboratory failed to document performing maintenance specified by the manufacturer for the Avantik QS12 Cryostat. 3. The laboratory reports performing 275 Moh's slide examinations annually.