Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	38D2046970	08/05/2024
Name of Provider or Supplier	**Street Address, City, State**	
Grace Dermatology & Micrographic Surgery Llc	2500 S Main Rd, Lebanon, OR	

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
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of laboratory records for maintenance of the Advantik QS11 Cryo-stat instrument used for Mohs surgery on site and interview with the Laboratory Director (LD), the laboratory failed to follow manufacturer's operating instructions for once yearly annual preventative maintenance (PM). Findings include: 1. Upon review of records for maintenance of the Advantik QS11 Cryo-stat serial # 60272 used in this lab when Mohs surgery is performed, no documented PM could be found since last survey 06/23/2022. Previous survey noted service was performed by Advantik Biogroup. 2. The User's Manual for the Advantik QS11 Cryo-stat, located in the laboratory's Mohs procedure manual, states on page 59, "For the examination and re-adjustment of the microtome, a routine PM should be performed by a trained service technician(s) once a year". 3. Interview with the LD at 2:30 pm revealed that the LD was aware of this requirement since last survey but does not wish for the service technicians from Advantik to do service annually as he prefers to perform the annual Cryo-stat maintenance when he feels it is appropriate or as needed. 4. The lab reports performing 366 Mohs surgeries annually.
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 inventory of chemicals kept in the flammables cabinet on site during survey and interview with the Laboratory Director (LD), the laboratory failed to ensure that no expired reagents or stains were used past their expiration dates, without validation of performance of any of these reagents or stains. Findings include: 1. Upon observation and inspection of the chemical products being stored in the flammables cabinet in the laboratory area, it was revealed that the following were currently in use but out of date / expired. Jugs are approximately equal to 1/2 gallon and unopened. Open partial jugs or bottles are identified with estimated volume during survey 08/05 /2024. a. Three (3) expired 1/2 gallon jugs of Acetone: two (2) half gallon jugs expired 03/15/2023, one (1) expired 04/03/2023. b. Three (3) expired 1/2 gallon jugs of Eosin stain, one (1) half gallon jug expired 05/31/2023, one half gallon jug 1/3 full expired 05/31/2023 and two (2) half gallon jugs expired 05/31/2024. c. One (1) half gallon jug of 100% Reagent alcohol expired 05/31/2024 d. One (1) half gallon jug of Gils Hematoxylin stain, 3/4 full, expired 12/2023 (day in December 2023 unable to be determined as stain had dripped over the date of 12/2023). e. One (1), one (1) ounce (1 oz.) bottle of potassium hydroxide (KOH), expired 03/31/2023. f. One (1) bottle (500 ml) of Wright's stain, 5/6 full, expired 01/2014, no day in January 2014 specified on the label. 2. Interview with the Laboratory Director (LD) at 2:30 pm revealed the LD was aware of these expired reagents but wished to use the expired stain and reagents. The LD also confirmed that there was no written verification procedure or process to verify validity as well as frequency of validity confirmation of expired reagents. 3. The laboratory reports performing 366 Mohs surgery procedures annually.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual and interview with the Laboratory Director (LD), the laboratory failed to validate the performance of expired stains and reagents used for Hematoxylin and Eosin (H&E) staining of human tissue during Mohs surgery. Findings include: 1. No verification studies confirming performance of the expired reagents and stains used in H&E staining of human tissue collected during Mohs surgery or a laboratory procedure for performing validation studies using expired reagents for Mohs tissue specimens was available for review during survey. 2. The LD confirmed during interview at 2:30 pm that there had not been any verification studies done on the expired reagents on site during survey. 3. See D5417