Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 38D1096273	(X3) Date Survey Completed 04/19/2023
Name of Provider or Supplier Oregon Dermatology & Surgery Llc	**Street Address, City, State** 360 S Garden Way Ste 230, Eugene, 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
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 review of written testing personnel (TP) competency records and interview with the Office Manager and Physicians Assistant (PA 1), the laboratory failed to ensure that bi-annual verification (2 x a year) for unregulated analytes occurred for testing personnel (TP) performing moderate and high complexity testing. Findings include: 1. Upon review of the Laboratory Director's (LD) peer review notebook provided by the Office Manager, it was noted that only one (1) peer review was performed in 2022, dated 09/06/2022. 2. Upon review for 2023, no peer review documentation was available for my review. 3. The Office Manager confirmed during interview at approximately 1230 pm 04/19/2023 that the LD had confirmed to her prior to my arrival for survey that he had not completed any bi-annual verification submissions to peers since the last one signed and dated 09/06/2022 by the reviewing Pathologist. 4. Upon request for the bi-annual competency records for PA 1 performing Potassium hydroxide (KOH) wet preps and scabies assessment, no evidence of competencies could be produced for 2022 or 2023. 5. Interview with PA 1 at approximately 1:00 pm confirmed that she had no evidence of peer review / bi-annual verification for KOH wet preps or scabies.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or

	examining specimens. This STANDARD is not met as evidenced by: Based on review of a written procedure manual provided during survey and interview with the Office Manager, the laboratory failed to ensure written procedures for all testing performed at this laboratory were available for testing personnel. Findings include: 1. Upon review of the procedure manual, no evidence of a written procedure for Potassium Hydroxide (KOH) wet preps could be found. 2. Upon review of the procedure manual, no evidence of a written procedure for Scabies assessment could be found. 3. Interview with the Office Manager at approximately 1:00 pm confirmed that there was no written procedure for either KOH or Scabies assessment.
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 inspection of three (3) patient treatment rooms stocked with Potassium Hydroxide (KOH) solutions available for use by providers performing wet preps, the laboratory failed to ensure the KOH solution was in date. Findings include: 1. Upon request for inspection of the rooms which have KOH solutions on the counter with glass slides for provider use, it was revealed that two (2) out of three (3) of the rooms had expired KOH solution. 2. The KOH solution from Delasco had an expiration date of June, 2019, for a total of three (3) years and ten (10) months out of date. 3. Upon request for a log of patients tested to determine the number of patients who may have been affected, no log could be produced. 4. The Physicians Assistant (PA1) present at the time of survey confirmed during interview at approximately 1:00 pm that no such log existed.