Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	38D0626694	08/23/2023
Name of Provider or Supplier	**Street Address, City, State**	
Cascade Dermatology And Aesthetics	4765 Village Plaza Loop Suite 100, 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
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on review of testing personnel (TP) competency records, the lack of any written Quality Assessment (QA) records/activities and interview with the Office Manager, the Laboratory failed to ensure that the laboratory was following it's standard operating procedure (SOP) titled "Quality Assurance" and following up with corrective action (CA) and documented QA activities. Findings include: 1. Upon request for written documentation of QA activities indicated in the laboratory's QA SOP, the laboratory failed to perform and document the yearly, quarterly and monthly QA activities listed therein. 2. Review of the twice yearly KOH reads by two (2) Physician Assistants (PA 1 & 2) revealed PA2 had no record of peer review by the LD in 2021 and 2022 for a total of four (4) missed peer reviews. No documentation of written CA or follow up for PA2 could be produced during survey. 3. Interview with the Office manager at 1100 on 08/23/2023 confirmed that PA2 had no peer review for KOH wet mounts in 2021 and 2022 and that no CA had been initiated. 3. The laboratory reports performing 400 wet mounts per year.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform

	test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of testing personnel (TP) competency records and interview with the Office Manager, the Laboratory Director (LD) failed to ensure that the two (2) Physician's Assistants (PA 1 & 2) performing potassium hydroxide (KOH) wet mounts had peer review twice yearly. Findings include: 1. Review of the twice yearly KOH peer review reads by two (2) Physician Assistants (PA 1 & 2) revealed PA2 had no record of peer review by the LD in 2021 and 2022 for a total of four (4) missed peer reviews for assessing competency with KOH mounts.There was no written record of Corrective Action (CA) for PA2 for my review. 2. Interview with the Office manager at 1100 on 08/23/2023 confirmed that PA2 had no peer review for KOH wet mounts or CA in 2021 and 2022. 3. The laboratory reports performing 400 wet mounts per year.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of testing personnel (TP) competency records and discussion with the Office Manager, the Laboratory Director (LD) failed to specify in writing, the laboratory assays each TP is authorized to perform on human specimens through all three (3) phases of laboratory testing. Findings include: 1. Upon request for a current delegation of duties list signed by the LD for the two (2) TP listed on the CMS 209 form, none could be produced. 2. Review of the twice yearly KOH peer review reads by two (2) Physician Assistants (PA 1 & 2) revealed PA2 had no record of peer review by the LD in 2021 and 2022 for a total of four (4) missed peer reviews for assessing competency with KOH mounts. 3. Interview with the Office Manager at 11: 10 am during survey 08/23/2023 confirmed that the laboratory did not have a current delegation of duties signed and dated by the LD. 4. The laboratory reports performing 400 KOH wet mounts per year.