Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	38D0624734	08/06/2018
Name of Provider or Supplier	**Street Address, City, State**	
Dermatology Associates	10215 Sw Hall Blvd, Tigard, 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
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 20% potassium hydroxide (KOH) reagents and discussion with one of the providers present during the survey 08/06/2018, the laboratory was using expired KOH material. Findings include: 1. Upon inspection of the two (2) dropper bottles of 20% KOH stored in the drawer by the microscope used by providers performing KOH wet mounts, both were found to be expired. Dropper bottle #1 expired 01/13/2018 (lot #293554). Dropper #2 expired 05/17/2018 (lot # 335254). 2. One of the providers present at survey confirmed using the expired reagent 08/06 /2018 at approximately 1430.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of records and discussion with staff, the Laboratory Director (LD) failed to fulfill the responsibilities required of the LD. This is a repeat citation. See D6079.

D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) 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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of records and discussion with staff, the Laboratory Director (LD) failed to follow the Plan of Correction (POC) submitted after the survey conducted previously on 09/12/2016 regarding biannual verification . Findings include: 1. The POC response to D5217, submitted 10/03/2016, included a new document titled KOH SIX MONTH COMPETENCY with a version date of 09/21/2016, stating that biannual verification would be documented every 6 months for providers performing potassium hydroxide (KOH) mounts. This policy/procedure was not followed through with written documentation. 2. The histotechnologist on site on the date of survey (08 /06/2018) confirmed that this policy/procedure was not followed since inception and that no biannual verification has been performed since the 09/12/2016 survey.
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: Based on review of records and discussion with staff, the Technical Supervisor (TS) failed to fulfill the responsibilities required of the TS. This is a repeat citation. See D6120
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4) The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results. This STANDARD is not met as evidenced by: Based on review of records and discussion with staff, the Technical Supervisor TS) failed to ensure positive and negative control organisms are used on mycology

	medium used to grow patient skin, nail and hair samples. Findings include: 1. Currently, the Laboratory uses only a positive dermatophyte control to test each new shipment/lot number of media form HealthLink. 2. The Laboratory has a procedure titled "Dermatophyte Culture" which specifies negative end user Quality Control (QC) to be used is E. coli (ATCC 25922) but they are not using this control. (page 3 of 5 of their procedure) 3. This was confirmed by the R.N. in charge of the Mycology media QC 08/06/2018 at approximately 1300
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of records and discussion with staff, the Technical Supervisor (TS) failed to fulfill the responsibilities required of the TS. This is a repeat citation. Findings include: 1. The TS failed to ensure all staff performing potassium hydroxide (KOH) wet mounts received bi-annual verification. 2. The Histotechnologist on site during the 08/06/2018 survey confirmed that no KOH bi-annual verification was performed or documented since the last survey 09/12/2016.