Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	22D0709066	06/21/2018
Name of Provider or Supplier	**Street Address, City, State**	
Kuchnir Dermatology And Dermatologic Surgery	125 Newbury Street, Framingham, MA	

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
D0000	A CLIA recertification survey was conducted for the Kuchnir Dermatology & Dermatologic Surgery laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. .
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 procedure review and interview, the laboratory failed to have policies and procedures in place to verify the accuracy of KOH and wet preps twice annually. The histotechnician and laboratory director interviewed on 6/21/18 at 9:15 am and 11:25 AM respectively confirmed that there was no established policy and procedure for verifying KOH and wet prep procedures twice annually. .
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or

	control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on procedure review and interview, the laboratory failed to have a procedure manual which included all aspects of the test procedure as evidenced by the following: A review of the procedure for performing KOH and wet preps failed to include a section describing the laboratory's system for entering results into the patient's medical record. The histotechnician and laboratory director interviewed on 6 /21/18 at 9:15 am and 11:25 AM respectively confirmed that the KOH and wet prep procedure did not include a section describing the laboratory's system for entering results into the patient's medical record. .
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 surveyor observation and record review, the laboratory failed to ensure laboratory reagents were not used when they had exceeded their expiration date. The findings include: During a tour of the laboratory on 6/21/18 at 8:40 a.m., the surveyor observed the following expired items in the laboratory area where Physician Performed Microscopy Procedures (PPMP) are performed: 1. One (1) bottle of Potassium Hydroxide (KOH), lot number K147M3, expiration date 7/17; 2. One (1) bottle of fungal stain (Chlorazol), lot number K16CL5, expiration date 12/31/17; and, 3. One (1) bottle of Swartz Lamkins fungal stain, lot number K15BB2, expiration date 11/17. There were no in-date reagents available in the laboratory. Based on this evidence the accuracy and reliability of microscopic examinations, utilizing these reagents and stains, could not be assured.