

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0864412	(X3) Date Survey Completed 10/14/2019
Name of Provider or Supplier James S Waldman Md	Street Address, City, State 22 Odyssey Ste 225, Irvine, CA	
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	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory documents, and interview with the laboratory personnel and the laboratory director, it was determined that the laboratory failed to perform and document, at least twice annually, to verify the accuracy of the KOH testing system in compliance with the evaluation of proficiency testing performance for KOH testing. The findings included: a. The laboratory performed KOH preparation to examine for presence or absence of fungal elements and ectoparasites. b. The qualified personnel in a physician office laboratory (POL) performed KOH, a PPM moderate complexity procedure, which is not listed in the subpart I of 42 CFR part 493. c. The laboratory testing personnel must verify at least twice annually and document for the accuracy of the testing. d. The laboratory affirmed (10/14/19 @ 11: 20 AM) that the laboratory failed to verify and document the evaluation of the KOH testing proficiency performance at least twice annually to verify the accuracy of its KOH testing.</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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.</p>

This STANDARD is not met as evidenced by:
Based on review of the laboratory documents, and interview with the laboratory personnel, it was determined that the laboratory failed to maintain written policies and procedures for Provider Performed Microscopy (PPM) including KOH preparation testing to examine the skin samples for fungal infections. The findings included: a. The laboratory is a dermatology laboratory, currently performs moderate complexity KOH preparation, PPM testing, for the examination of the presence or the absence of yeast and parasites such as scabies, plus high complexity testing of histopathology including Mohs procedures and tissue biopsy examinations. b. The laboratory, at the time of survey (10/14/209 @ 11:30 AM) failed to provide records of KOH testing documents including, but not limited to the procedure manual and a list of patient log including the name list, date of the services, site of the sample, test results, and the testing person.

D5415

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(c)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:
Based on observation of the laboratory's KOH reagent, and interview with the laboratory personnel, it was determined that the laboratory failed to indicate and label that the reagents when was prepared or opened and when is expired, and ensure the validity of the reagent quality. The findings included: a. The laboratory performed KOH preparation for skin fungal or parasite infactions. b. The laboratory used KOH reagent to prepare for the testing. c. The laboratory failed to indicate the opened date and assess the quality of the reagent solution which apperaed cloudy (contaminated).

D5891

POSTANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1299(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.

This STANDARD is not met as evidenced by:
Based on review of the laboratory documents, and interview with the laboratory personnel, it was determined that the laboratory failed to maintain and follow its written policies and procedures (P&P) to ensure the accuracy of the patient testing reports. The findings included: a. The laboratory performed Mohs procedures to its patients. b. The Mohs procedures included Mohs mapping and clearance of the tissue removed from the infected areas by examine the H & E stained tissue slides. c. Review of 4 patient's Mohs maps and the tissue slides, two out of the four documents retrieved were found to have inconsistent information. d. One patient document with ID J#1822-19 indicated the date of service on 10-2-19 on the tissue slides, while 10/1 on the Mohs map report sheet. e. The another patient with ID J # 1782-19 indicated the date of service on 9-18-19 on the tissue slides, while 9/17 on the Mohs map report

sheet. f. The laboratory personnel affirmed (10/14/2019 @ 11:10 AM) that the discrepancies of these two patient Mohs documents existed.

D6004

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reappoints 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 observation of the laboratory reagent, review of the laboratory's records, and interview with the laboratory testing personnel, and the laboratory director, it was determined that the laboratory director failed to be responsible for the overall operation including assurance of the accuracy of the patient test reports, accurately, and proficiently, and assuring compliance of the applicable CLIA and state regulations (if any). The findings included: a. The laboratory performed KOH, a PPM moderate complexity procedure, without an appropriate procedure manual available at the time of survey (10/14/2019 @ 11:30 AM), see D-5401. b. The KOH procedure is not listed in the subpart I of 42 CFR part 493, the laboratory failed to at least twice annually to verify the accuracy of the KOH testing system, see D-5217. c. The laboratory failed to indicate by labeling the open date of the reagent and failed to assess the quality and the condition of the reagent used for KOH procedure, see D-5415. d. The laboratory failed to follow and maintain its quality assessment to verify the accuracy of the laboratory test reports in two out of 4 Mohs procedure reports reviewed, see D-5891.