Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2129629	(X3) Date Survey Completed 01/11/2018
Name of Provider or Supplier Amy M Reinstadler Md Inc	**Street Address, City, State** 361 Hospital Rd Ste 533, Newport Beach, 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
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures (P&P) and interview with the laboratory staff, it was determined that the laboratory failed. To update the P&P to reflect the current procedures are followed. The findings included: a. Interview with the laboratory director for the laboratory's P&P to evaluate its proficiency test performance annually to ensure the accuracy of the test procedures. b. An inconsistent procedures noted as to the current and previous by the laboratory director to evaluate the proficiency of test performance. c. The current procedures to evaluate the proficiency of test performance is to use split samples sent to one identified peer which is no longer the same one peer identified in the previous P&P approved and signed by the current laboratory director in 2016. d. The laboratory director failed to approve, sign and date the current laboratory procedures or changed procedures.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system

	performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory temperature records, and interview with the laboratory staff, it was determined that the laboratory failed to detect over time the accuracy and precision of the test performance that may be influenced by changes in test system performance and environment conditions, and variance in operation performance. The findings included: a. The laboratory implemented a DTM procedure for detection of dermatophytic fungi. b. The laboratory use Sabourund Dextrose agar tubes as a medium to detect the dermatophytic fungi. c. Review of the laboratory's temperature records for the acceptable temperature ranges pertaining to the storage of the media and the test procedure, there were no acceptable temperature monitor readings available to ensure the accuracy and precision of the DTM test performance.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of the patient test result reports, and interview with the laboratory staff, it was determined that the laboratory failed to include the following but are not limited to: 1) the name and address of the laboratory location where the test was performed, 2) the test report date. The findings included: a. The laboratory perform dermatopathology testing and report the biopsy results reports. b. Review of the laboratory's biopsy patient test result reports, there were no name and the location of the laboratory where the rest was performed. c. No report date clearly indicated when the report was completed
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. This STANDARD is not met as evidenced by: Based on review of the laboratory's records, written policies and procedures, and interview with the laboratory director, it was determined that the laboratory director failed to ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test

	performance, which includes the preanalytic, analytic, and postanalytic phases of testing. The findings included: See D-5407, D-5441, and D-5805