Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D2107203	(X3) Date Survey Completed 01/17/2020
Name of Provider or Supplier Intermountain Salt Lake Clinic Dermatology	**Street Address, City, State** 389 South 900 East, Salt Lake City, UT	

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	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 lack of documentation and interview with staff, the laboratory failed to verify histopathology test accuracy at least twice annually in 2019. The laboratory performs approximately 3000 tests per year. Findings include: 1. The laboratory failed to verify histopathology twice in 2019. 2. In an interivew with the technical consultant on 01/17/2020 at approximately 12:15 P.M. staff confirmed the laboratory lacked documentation they verified skin biopsy histopathology diagnoses accuracy the second event of 2019.
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 reagent record log review, lack of documentation, and interview with staff the laboratory failed to ensure potassium hydroxide (KOH) reagents were not in use after their expiration dates for 3 of 4 lot numbers of KOH reagents reviewed from January 2018 to January 2020. findings include: 1. Reagent log review included documentation KOH reagents were used past their expiration date for lot #34890 that expired 08/18 and a new lot number was not in use until 11/14/2018; for lot number

	35874 that expired 12/18 and a new lot number was not placed in use until 03/20 /2019; and for lot number 37579 expired on 07/29/2019 and a new lot number was not placed in use until 07/31/2019. 2. Patient test records included documentation patient 54077133 was tested using KOH reagent on 10/08/2018. The laboratory did not record each day of testing for KOH reagent. It could not be determined if testing was performed after the expiration dates for lots 35874 and 37579. 3. In an interview conducted on 01/17/2020 at approximately 12:15 P.M., the technical consultant confirmed the KOH regent expired before a replacement was installed.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on lack of records and dates of potassium hydroxide (KOH) testing and interview with staff, the laboratory failed to maintain a record system that included all specimens that had KOH tests for identification of the presence or absence of fungal elements. Findings include: 1. The laboratory lacked a record system to capture the dates KOH tests were performed for identification of the presence or absence of fungal elements from January 2018 to January 2020. 2. In an interview with staff on 01 /17/2020 at approximately 11:00 A.M. staff stated the laboratory method of identification for tests that were performed included a search for KOH tests that were billed. The laboratory assistant located 3 specimens for review by searching for patients via recollection and record searches for the presence of a KOH test result. in the laboratory information system.