Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	46D0972534	01/15/2018
Name of Provider or Supplier	**Street Address, City, State**	
Dermatology Center Of Salt Lake	7396 S Union Park Ave #201, Midvale, 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
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 lack of documentation and interview with staff, the laboratory failed to record the lot numbers and expiration dates for 4 of 5 reagents reviewed: Hematoxylin and Eosin stains, Potassium Hydroxide (KOH) reagent, and Chlorizol Black reagents in use from January 2016 to January 2018. The laboratory tested approximately 100 Mohs samples per year staining with Hematoxylin and 100 KOH and Chlorizol Black specimens per year. Findings include: 1. The laboratory did not record each lot number and expiration date of Hematoxylin, Eosin, KOH,and Chlorizol Black reagent since January 2016. The current practice was to record the date the reagent was placed in use on the reagent bottle. The laboratory did not retain used reagent bottles as a record for the lot numbers and expiration dates and the dates the reagents were placed in use. On the day of survey the laboratory did not have an open container of hematoxylin reagent in the laboratory to determine if the reagent was used past the expiration date. 2. In an interview with staff on 01/15/2018 at approximately 2:00 P. M. Staff confirmed they did not maintain the reagent log and wrote the received date on the reagent bottles. Staff confirmed they did not have hematoxylin reagent available.
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 patient test record review and interview with staff, the laboratory failed to record the identity of the personnel performing 6 of 6 dermatophyte test media (DTM) fungal culture tests reviewed from 04/19/2016 to 10/23/2017. Findings include: 1. Test reports reviewed for DTM fungal cultures collected on 04/19/2016, 09/29/2016, 11/14/2016, 03/09/2017, 04/26/2017 and 10/23/2017 failed to include the identity of the person performing the tests. 2. In an interview with staff on 01/15/2018 at approximately 2:00 P.M. staff stated the director performed all except approximately 5 DTM tests per year. The laboratory failed to include the identity of the testing personnel in the test records.
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 patient test reports review, laboratory procedure manual review, Dermatophyte Test Media package insert review, and interview with staff, the laboratory failed to accurately report the test requested for five of six dermatophyte test media cultures reports reviewed. Findings include: 1. Patient test reports reviewed for patients: Date of Birth (DOB) 05/27/1946 cultured on 04/19/2016; DOB 05/04 /2008 on 09/29/2016; DOB 09/19/2014 on 11/14/2016; DOB 03/23/1984 on 04/26 /2017; and DOB 07/10/1988 had the test request listed as, "PCR Dermatophyte chitin synthase 1 gene". The result was reported as either "No Growth, No color change"for the tests cultured on 04/19/2016, 02/29/2016, 11/14/2016, and 04/26/2017, and reported as "Tinea" for the specimen cultured on 10/23/2017. 2. The laboratory procedure manual review failed to include procedures for performing PCR (polymerase chain reaction) tests of any kind or procedures for reporting mycology cultures beyond the genus level of identification (i.e., Dermatophytes). 3. Dermatophyte test media pack insert review included instructions that the culture indicated the presence or absence of dermatophytes by growth and color change from amber to red. Growth with no color change indicated the presence of yeast or mold. Tinea is the diagnosis of a fungal infection. A DTM culture does not provide this test result. 4 In an interview with staff on 01/15/2018 at approximately 2:00 P.M. staff stated the electronic medical record did not have an option to select dermatophyte culture as the test requested. The test reports contain the test as requested by the lab not the actual test requested. The lab reported the actual dermatophyte test media culture result as no growth or growth and no color change or color change.

D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on lack of documentation and interview with staff, the laboratory technical consultant failed to evaluate competency for 1 of 1 test person performing dermatophyte media (DTM) fungal cultures at least once a year after the first year of performing DTM tests for 2 of 2 years of testing reviewed (2016 and 2017) . Findings include: 1. The laboratory lacked documentation one testing person was evaluated annually for DTM culture reading competency. 2. In an interview conducted on 01/15 /2018 at approximately 1:30 P.M. staff stated the director performed all but approximately 5 DTM culture tests per year. Those approximately 5 tests were performed by the Nurse practitioner. Staff confirmed the laboratory did not have documentation of annual DTM competency for the testing person.