Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	46D0525211	04/20/2018
Name of Provider or Supplier	**Street Address, City, State**	
Lone Peak Dermatology	11760 S 700 E Suite 210, Draper, 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
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 procedure manual review, lack of documentation, and interview with staff, the current laboratory director failed to sign and date as approved the procedure manual before use for 1 of 2 tests performed (histopathology). The laboratory began histopathology testing in 07/2017 and had reported approximately 100 cases. Findings include: 1. The laboratory procedure for performing Mohs testing (histopathology) was a copy of a procedure manual used in another Mohs laboratory which had been signed by the technical supervisor in 2011. 2. The technical supervisor confirmed on 04/20/2018 at approximately 10:00 am, the procedure manual had not been customized for Lone Peak Dermatology and had not been approved by the director.
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 Mohs surgery test report and Mohs surgical map review, and interview with staff, the test report for 4 of 4 Mohs surgery cases reviewed failed to include the name and address of the laboratory location where the test was performed. Findings include: 1. Mohs maps for cases 1 and 32 from 2017 and cases 2 and 35 from 2018 have Granger Medical Surgical Dermatology printed on the map. 2. Mohs test reports for cases 1 and 32 of 2017 list the test location as Granger Medical West Valley - Dermatology at 3725 W. 4100 S. West Valley City, UT 84120-5530. 3. Staff confirmed on 04/20/2018 at approximately 11:00 am, the 4 cases had been tested at Lone Peak Dermatology.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on procedure manual review, lack of documentation, and interview with staff, the director failed to establish a quality assessment program to identify failures in quality when they occur in the pre-analytical, analytical, and post-analytical phases of testing for 2 of 2 tests performed (potassium hydroxide preparation and histopathology testing). Findings include: 1. The laboratory lacked a written quality plan to monitor testing from specimen collection to final report. 2. The director confirmed on 04/20/2018 at approximately 11:00 am, the laboratory did not have a written plan or audit process to identify and correct problems in the laboratory.