Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	46D2142280	04/04/2019
Name of Provider or Supplier	**Street Address, City, State**	
Draper Dermatology	1325 W South Jordan Parkway, Suite 103, South Jordan, 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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on lack of documentation and interview with staff, the laboratory failed to retain, for at least 2 years, the paperwork returned with their histopathology slides from their reference laboratory for 4 of 4 biopsy samples reviewed. Findings include: 1. The reference laboratory sends paperwork with the slides prepared, which includes the unique identification number on the slide and the gross description of the biopsy sample. 2. The director stated on 04/04/2019 at approximately 4:00 p.m., he used the paperwork for reference while reading the slides, but did not retain it after the test was reported.
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on lack of documentation, histopathology slide review, patient test report review, and interview with staff, the laboratory failed to establish and follow written

	policies to ensure positive identification of patient slides for histopathology testing for 6 months of testing performed from 10/2018-04/2019. Findings include: 1. The laboratory sends biopsy samples to a reference laboratory for sample processing and slide preparation. At the director's request, some of the slides are sent back to the laboratory for diagnosis by the director. Slides are labeled with the last name and a unique identification number by the reference laboratory. The paperwork that is sent with the slides also contains the unique identification number. 2. The laboratory failed to retain the original paperwork returned with the slide after the cases had been reported, and failed to establish a procedure to link the biopsy with the identification number on the slide. (See D3031) 3. Patient test reports document biopsy samples taken on 10/18/2018, and test results reported by the laboratory, from 2 patients with the same last name (LU-18-000008 and LU-18-200010). The laboratory was unable to determine which slide went with which biopsy sample. 4. The director confirmed on 04/04/2019 at approximately 3:30 p.m., the laboratory failed to establish a written procedure to ensure histopathology slides could be traced back to the biopsy sample.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on Bethesda Dermatopathology Laboratory (BDL) proficiency testing (PT) result review and interview with staff, the laboratory failed to document test results had been evaluated for 1 of 1 histopathology testing events reviewed in 2018. Finding include: 1. BDL sends 10 histopathology cases for evaluation to laboratories enrolled in their program 3 times a year. 2. Results from the laboratory's 2018 testing event document a score of 5 out 10 correct answers. 3. The laboratory lacked documentation that discrepant (or not submitted) results had been evaluated by the director. 4. The director stated on 04/04/2018 at approximately 3:30 p.m., he had not documented the reason results were incorrect.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) 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. This STANDARD is not met as evidenced by: Based on lack of documentation and interview with staff, the laboratory failed to have a written procedure manual for histopathology testing. The laboratory started reporting tests in 10/2018 and had reported approximately 10 biopsy results. Findings include: 1. The laboratory did not have any written procedures for the pre-analytical, analytical, and post-analytical phases of histopathology testing. 2. Staff confirmed on 04/04/2019 at approximately 2:30 p.m. they did not have any written procedures.
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f)

	(a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on lack of documentation and interview with staff, the laboratory lacked documentation of Hematoxylin and Eosin (H&E) stain quality evaluation for 6 months of testing reviewed. The laboratory had reported approximately 10 biopsy results from 10/2018-04/2019. Findings include: 1. The laboratory lacked H&E stain quality evaluation documentation for histopathology tests reported by the laboratory. 2. The director confirmed on 04/04/2019 at approximately 3:30 p.m., evaluation of the stain quality was not recorded by the laboratory when the slides were read and they did not request stain control records from their slide preparation laboratory.
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 report review, and interview with staff, the laboratory failed to include the test results, as well as the name and address of the laboratory where the gross examination was performed, for 4 of 4 histopathology test reports reviewed. Findings include: 1. Test reports for patients SJ-18-000648, LU-18-000009, LU -18-000008 and LU-18-000010 failed to include results under the Gross Examination section of the report. 2. The director stated on 04/04/2019 at approximately 3:00 p.m., the biopsy samples were sent to a reference laboratory for processing, staining, and gross examination. The results of the gross examinations were included in the reurned paperwork, along with the processed slides, but not included in the final test report.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

	This STANDARD is not met as evidenced by: Based on lack of documentation and interview with staff, the laboratory director failed to ensure a quality assessment program was established to assure quality of laboratory services through the pre-analytical, analytical, and post-analytical phases of histopathology testing. The laboratory began testing on 10/2018 and had reported approximately 10 biopsy results. Findings include: 1. The laboratory lacked a written plan for how they monitor the quality of testing provided. 2. Staff confirmed during an interview on 04/04/2019 at approximately 3:00 p.m., they did not have a written policy on how they ensure quality testing.