Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	46D0525457	09/21/2022
Name of Provider or Supplier	**Street Address, City, State**	
Stone Dermatology	1375 N University Ave, Provo, 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
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 written procedures for Potassium Hydroxide (KOH) and Dermatophyte Test Medium (DTM) testing. The laboratory performs approximately 20 KOH and DTM tests annually. Findings include: 1. The laboratory failed to have written procedures for KOH and DTM testing. 2. Lead Medical Assistant not listed on the Laboratory Personnel Report (CMS-209) confirmed during an interview on 09/21/2022 at approximately 12:10 p.m., the laboratory did not have written procedures for KOH and DTM testing.
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 plan was established to assure quality of laboratory services through the pre-analytical, analytical, and post-analytical phases. The laboratory performs approximately 4,000 histopathology and 20 mycology tests annually. Findings include: 1. The procedure manual failed to include a written Quality Assessment (QA) plan. 2. Laboratory Director confirmed during an interview on 09/21/2022 at approximately 12:00 p.m., the laboratory did not have a written QA plan.