Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D2171278	(X3) Date Survey Completed 08/21/2023
Name of Provider or Supplier Smart Skin Dermatology	**Street Address, City, State** 3200 Clubhouse Drive Ste 100, Lehi, 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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on a review of the laboratory Standard Operating Procedure (SOP) manual and an interview with the Clinical Operations Manager (COM), the laboratory had failed to establish written policies and procedures to assess employee competency for Hematoxylin and Eosin (H&E) slide reading and Potassium Hydroxide (KOH) testing during 2022. Findings include: 1. A review of the SOP manual at 10:30 AM on 8/21 /23 revealed that the laboratory had failed to establish written policies and procedures to assess employee competency for H&E and KOH testing. 2. An interview with the COM at 11:00 AM on 8/21/23 confirmed that the laboratory had failed to establish written policies and procedures to assess employee competency for H&E and KOH testing.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on a review of the laboratory Standard Operating Procedure (SOP) manual and

	an interview with the Clinical Operations Manager (COM), the laboratory had failed to establish written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements (Quality Assurance Policy). Findings include: 1. A review of the SOP manual at 10:30 AM on 8/21/23 revealed that the laboratory had failed to establish written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements. 2. An interview with the COM at 11:00 AM on 8/21/23 confirmed that the laboratory had failed to establish written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements.
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 a review of the laboratory Standard Operating Procedure (SOP) manual and an interview with the Clinical Operations Manager (COM), the laboratory had failed to establish a written procedures manual for Hematoxylin and Eosin (H&E) slide preparation and staining, and Potassium Hydroxide (KOH) testing. The laboratory performs 144 H&E tests and 6 KOH tests annually. Findings include: 1. A review of the SOP manual at 10:00 AM on 8/21/23 revealed that the laboratory had failed to establish a written procedures manual for H&E slide preparation and staining, and KOH testing. 2. An interview with the COM at 11:00 AM on 8/21/23 confirmed that the laboratory had failed to establish a written procedures manual for H&E slide preparation and staining, and KOH testing.