Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D0524596	(X3) Date Survey Completed 03/14/2022
Name of Provider or Supplier Swinyer Woseth Dermatology	**Street Address, City, State** 1548 E 4500 S Suite 201/202, Salt Lake City, 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
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 a review of Proficiency Testing (PT) documentation and interview with the Practice Manager, the laboratory failed to document evaluation and verification activities for unacceptable results obtained on the Potassium Hydroxide (KOH) proficiency testing performed. Finding include: 1. Review of the PT evaluations on 03/14/22 at 10:30 am revealed that the laboratory failed to document evaluation and verification activities for the unacceptable score of 50% on the Potassium Hydroxide (KOH) proficiency testing performed on the American Proficiency Institute (API) 2021 Microbiology 2nd event. 2. In an interview with the Practice Manager on 03/14/22 at approximately 2:00 pm, it was confirmed that the laboratory failed to document evaluation and verification activities for the unacceptable result.
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 Quality Assurance documentation and interview with the histotechnologist, the laboratory failed to follow their policy regarding laboratory director sign off of the quality assurance checklist. Finding include: 1. Review of the

	monthly quality assurance checklists on 03/14/22 at 1:40 pm revealed that the laboratory director failed to sign off the checklists. 2. The laboratory Quality Assurance policy states, "The lab director will also review and sign off the checklist monthly. 3. In an interview with the histotechnologist on 03/14/22 at approximately 1: 45 pm, it was confirmed that the lab had failed to follow their Quality Assurance policy. 4. The lab director singed off 0 of 12 monthly Quality Assurance checklists during 2021.
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 a review of Standard Operating Procedures (SOP) and interview with the Practice Manager, the laboratory failed to have the SOP titled, "Checking Fungal culture bottle received from Acuderm," signed and dated by the laboratory director before use. Finding include: 1. Review of the SOP manual on 03/14/22 at 12:35 pm revealed that the laboratory director failed to sign and date the SOP titled "Checking Fungal culture bottle received from Acuderm." 2. In an interview with the Practice Manager on 03/14/22 at approximately 2:00 pm, it was confirmed that the lab director had failed to sign and date the SOP before use.