Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2141433	07/12/2024
Name of Provider or Supplier	**Street Address, City, State**	
Valley Skin Institute	7777 N Ingram Ave, Fresno, CA	

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
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on the surveyor's interview with the office manager (OM) and record review of pre-analytic, analytic, and postanalytic phases of testing on July 12, 2024, at approximately 9:30 a.m., the laboratory failed to establish a complete written policies and procedures for an ongoing quality assessment mechanism to monitor, assess, and when indicated, correct problems identified in the laboratory's systems. Findings included: 1. Based on the review of ten (10) randomly chosen patient reports and interview with the OM at approximately 9:30 a.m. on July 12, 2024, the quality assessment policies and procedures found at the time of survey was incomplete. 2. The OM affirmed that the quality assessment procedure found at the time of the survey does not state any detailed procedure on how to monitor, assess and correct patients' issues identified and no documentation is kept for any records checked per month. 3. According to the laboratory testing declaration submitted on July 12, 2024, the laboratory performed approximately 2,515 Mycology, Parasitology and Dermatopathology patient tests annually.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

	This STANDARD is not met as evidenced by: Based on the surveyor's review of ten (10) randomly chosen patient records and interview with the office manager (OM), it was determined that the laboratory failed to perform and document preventive maintenance (PM) as defined by the manufacturer and with at least the frequency specified by the manufacturer for the laboratory's small equipment. The findings included: 1. The laboratory's policies and procedures indicated that the PM for the microscope will be performed as needed aside from the annual PM performed by the service company. Upon review of records and documentation, it was determined that the dates of testing does not match the log sheet. 2. The OM affirmed on July 12, 2024, at approximately 10:30 a.m. that maintenance performed for the microscope only recorded the dates when Mohs testing is performed. It does not reflect the other dates when it was used for KOH and scabies testing. 3. Based on the review of five out of 10 randomly chosen patient records, any record of preventive maintenance performed for the microscope were not found. Therefore, the quality of patient testing was not assured. 4. Based on the review of randomly chosen patient records, three out of 10 had missing entry log for stain preventive maintenance. Therefore, the quality of patient testing performed were not assured. 5. According to the test volume declared by the laboratory on July 12, 2024, the laboratory performed approximately 15 tests for KOH and scabies, and 2,500 dermatopathology tests annually.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. This STANDARD is not met as evidenced by: Based on the interview with the office manager, review of the laboratory's policies and procedures, observations during the tour of the facility, and review of ten randomly chosen patient records on July 12, 2024; the laboratory director is herein cited for failure to ensure that several aspects of the preanalytic, analytic, and postanalytic phases of the laboratory testing were monitored. Findings included: 1. Incomplete quality assessment policies and procedures. See D5391. 2. Missing preventive maintenance records. See D5429. .
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on the interview with the office manager and review of laboratory's personnel

	competency records on July 12, 2024 at approximately 9:30 a.m., the laboratory director is herein cited for failure to ensure that established written policies and procedures were not followed for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency. Findings included: 1. Based on the review of competency assessment records, it was determined that the practice of the laboratory was to use one template for all personnel that included Universal Precautions/Infection Control, Obtaining vital signs, Medication Management, Performing Wound care, Medical equipment use/testing for autoclave, Emergency response, and, CLIA laboratory compliance that only included waived pregnancy test and handling and labelling of samples. 2. The OM also functioned as Mohs technician and affirmed on July 12, 2024 at approximately 9:30 a.m., that no separate competency assessment covering other duties and responsibilities such as operating the cryostat, processing and staining for blocks and slides, maintenance, etc. was available. 3. According to the annual testing declaration submitted at the day of survey, the laboratory performed 15 tests for KOH and scabies, and 2,500 histopathology test samples.