Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D0662724	09/06/2023
Name of Provider or Supplier	**Street Address, City, State**	
Saguaro Dermatology	2150 S Dobson Rd Ste 1, Mesa, AZ	

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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on lack of accuracy verification documentation for Mohs testing and interview with the facility personnel, the laboratory failed to verify the accuracy of testing performed under the subspecialty of Histopathology at least twice annually during 2021 and 2022. Findings include: 1. No documentation was presented for review to indicate the laboratory verified the accuracy of the microscopic interpretation (reading /diagnosis) of Mohs specimens at least twice annually during 2021 and 2022. 2. The facility personnel interviewed on September 6, 2023 at 11:00 AM confirmed that the laboratory failed to verify the accuracy of Mohs testing at least twice annually during 2021 and 2022. 3. The laboratory's reported annual test volume under the subspecialty of Histopathology is 572.
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 review of established quality assessment (QA) policies and procedures and interview with the facility personnel, the laboratory failed to monitor, assess and

	correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. Findings include: 1. The laboratory performs testing under the subspecialty of Histopathology, with an approximate annual test volume of 572. The laboratory performs the microscopic interpretation (reading/diagnosis) of histopathology specimens which are read during the Mohs procedure. 2. The laboratory's established QA policy presented for review during the survey states, "Each Mohs surgeon will have 6 slides from each year (3 from Jan-June and 3 from July-Dec) in which Mohs surgery is performed pulled at random. The slides will be checked for accuracy....A reviewing Mohs surgeon will verify the diagnosis and sign off on the paperwork." 3. The laboratory failed to follow the established QA policy indicated above as evidenced by the laboratory's failure to verify the accuracy of Mohs cases in 2021 and 2022. See D5217 for findings. 4. No QA documentation was presented for review during the survey to indicate the laboratory has 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. 5. The facility personnel interviewed on September 6, 2023 at 11:30 AM confirmed the laboratory failed to follow their established QA policy and procedure referenced above, and confirmed the laboratory's QA processes at the time of the survey failed to monitor, assess and correct problems as they occur in the general laboratory systems.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on lack of Quality Control (QC) documentation and interview with the facility personnel, the laboratory failed to document the acceptability of staining materials for intended reactivity to ensure predictable staining characteristics for testing performed in the subspecialty of Histopathology. Findings include: 1. The laboratory performs Mohs testing in the subspecialty of Histopathology, with an approximate annual test volume of 1000. 2. No documentation of the Hematoxylin & Eosin (H&E) stain acceptability was presented for review for testing that occurred on 05/24/2022. 3. A total of 4 patients were tested on 05/24/2022. 4. The facility personnel interviewed on September 6, 2023 at 11:15 AM confirmed the laboratory failed to evaluate and document the H & E stain acceptability on the date indicated above.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality assessment (QA) records, review of the

	Quality Control Staining log and interview with the facility personnel, the laboratory's QA processes failed to monitor, identify and correct errors found in the analytic systems specified in 493.1251 through 493.1283. Findings include: 1. The laboratory failed to document the acceptability of the H&E stain used on patient specimens on each day of use in May 2022. See D5473 for specific findings. 2. The laboratory's QA process failed to include an ongoing mechanism to monitor, identify and correct errors found in the analytic systems specified in 493.1251 through 493.1283, including but not limited to, the performance and documentation of the H&E stain acceptability. 3. The facility personnel interviewed on September 06, 2023 at 11:30 AM confirmed the laboratory's QA process at the time of the survey failed to monitor, identify and correct errors found in the analytic systems specified in 493.1251 through 493.1283.