Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D0530945	10/29/2020
Name of Provider or Supplier	**Street Address, City, State**	
All Dermatology	6320-A W Union Hills Dr Ste 210, Glendale, 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
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on direct observation of stain reagents and interview with the facility personnel, the laboratory used the stain reagent, Hematoxylin, past the expiration date. Findings include: 1. The laboratory performs the Hematoxylin and Eosin (H&E) stain on patient slides in conjunction with Mohs testing, with an approximate annual test volume of 3,707 tests. 2. During the survey conducted on October 29, 2020, direct inspection of the Hematoxylin reagent, lot #7575-00, indicated an expiration date of April 2019. 3. The facility personnel confirmed that the expired reagent indicated above was still in use on the day of the survey. The number of patients tested using the expired reagent could not be determined at the time of the survey.
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 Quality Assessment (QA) policies and procedures and interview with the facility personnel, the laboratory failed to follow policies and procedures for

	an ongoing mechanism to monitor, assess, and correct problems identified in the analytic systems. Findings include: 1. The laboratory's established policy titled, "Quality Assessment Program" states, "The Laboratory Director will review all Quality Control/H & E records that have not been reviewed previously." 2. The laboratory utilized a Quality Control log to document the H&E Stain Acceptability until February 2020. The laboratory stopped documenting the H&E stain acceptability on the log from 2/17/20 through the date of the survey on 10/29/20. During that time, the laboratory director was initialing the H&E Quality Control slide made each day of patient testing. Interview with the facility personnel indicated that the Laboratory Director's initials were being documented on the QC slide as evidence of the H&E stain acceptability for that day of testing. 3. No documentation was presented for review to indicate the laboratory director was following the established QA procedure by reviewing the Quality Control/H&E records (log) as indicated in the policy above. 4. No revised QA policy and procedure was presented for review to indicate the laboratory changed the documentation procedure for the H&E stain acceptability, as evidenced from February 2020 through October 2020. 5. The facility personnel confirmed that the laboratory failed to follow established QA policies and procedures as indicated above.