Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D0530945	05/03/2018
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
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 the laboratory's established Quality Assessment (QA) policies and interview with the facility personnel, the laboratory failed to establish policies for amending test reports related to discrepancies identified during the accuracy verification process for Dermatopathology testing performed by the laboratory. Findings include: 1. The laboratory performs testing on patient specimens under the sub-specialty of Histopathology, with an approximate annual test volume of 3,257. 2. The policy titled, "Slide Review for Histopathology (including Frozen Sections) & Histopathology for Mohs" reviewed during the survey states, "ADS send two cases annually, per physician/testing personnel, per test...to be reviewed by a local dermatopathologist. ...In the event of a conflicting diagnosis, including diagnosis terminology or possible treatment, the following steps will be taken: 1). The PT section on the corrective action form will be completed for that particular case. Each area will be reviewed by the performing physician. If necessary, another ADS physician will review the case as well. 2). An additional case from the same physician within a close time frame will be reviewed by another ADS physician, and logged. 3). If additional errors are found, then the physicians will meet to review more recent cases and discuss if a voluntary cease of testing is required." 3. The policy referenced above failed to indicate the process of amending the test report, if applicable, in the event of a noted discrepancy. 4. The laboratory's corrective action form used for proficiency testing errors includes the following assessments: "Has the patient chart been reviewed, Do the results effect patient treatment or care, Was the patient

	notified, Has a 3rd party reviewed the case, and Is further training needed?" 5. The corrective action form referenced above failed to include information regarding whether or not the test report was amended due to the identified error. 6. The facility personnel confirmed that the laboratory's established QA policies and procedures lacked information regarding the amendment of the test report in the event of a diagnostic discrepancy.
D5821	TEST REPORT CFR(s): 493.1291(k) When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report. This STANDARD is not met as evidenced by: Based on review of patient test reports, review of accuracy verification documentation and interview with the facility personnel, the laboratory failed to issue amended test reports for testing performed in the sub-specialty of Histopathology. Findings include: 1. The laboratory performs testing on patient specimens under the sub-specialty of Histopathology, with an approximate annual test volume of 3,257. It is the practice of the laboratory to select two cases annually, per physician, per test for review by another dermatopathologist for accuracy verification. 2. Review of the test report and accuracy verification documentation for case #16-2328 revealed the patient test report listed the original diagnosis as "Squamous cell carcinoma (well-differentiated)". The reviewer's diagnosis for the same case was "Verrucous keratosis with fibrosis, superficial biopsy; negative for malignancy". 3. Review of the test report and accuracy verification documentation for case #17-2591 revealed the patient test report listed the original diagnosis as "Squamous cell carcinoma with associated cutaneous horn (poorly-differentiated)". The reviewer's diagnosis for the same case was "Verruca vulgari". 4. No documentation was presented for review during the survey to indicate the laboratory issued an amended report as a result of the diagnosis discrepancies identified for case #16-2328 or case #17-2591. 5. The facility personnel confirmed that the laboratory failed to issue an amended test report for each case stated above.