Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 03D1094571	**(X3) Date Survey Completed** 08/02/2019
Name of Provider or Supplier Updegraff Clinic For Allergy And Dermatology	**Street Address, City, State** 14506 W Granite Valley Dr Ste 110, Sun City West, 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 quality assessment (QA) policies and interview with the facility personnel, the laboratory (A)failed to perform and document quality assessment activities as indicated in laboratory policy and (B) failed to perform and document accuracy verification activities as indicated in laboratory policy. Findings include: 1. The laboratory performs patient testing in the sub-specialty of Histopathology with an approximate annual test volume of 504. A1. The laboratory's established policy titled, "Quality Assessment Procedures" indicates that each of the laboratory's quality systems will undergo an assessment review quarterly to maintain and improve laboratory performance and services. The quarterly review includes the monitoring of patient test management, Quality Control, Proficiency Testing, test requisitions, test reports, reagents, personnel, and complaints. A2. No quarterly QA documentation was presented for review from 2017 through the date of the survey conducted on August 2, 2019. The last documented QA review was performed in 2016. A3. The facility personnel confirmed that the laboratory failed to perform and document the quarterly QA review as stated in policy. B1. The laboratory's established policy titled, "Proficiency Testing for Quality Assessment" states, "We send a previously tested patient slide to Arizona Dermatopathology Laboratory and annotate the results to assure they are in correlation with one another. We randomly choose one patient previously tested slide a month to send to Arizona Dermatopathology Laboratory." B2. No documentation was presented for review from the date of the previous survey

	conducted in February 2017 to the date of the current survey conducted on August 2, 2019 to indicate the laboratory followed their established policy and sent one patient slide a month to another laboratory to verify the accuracy of the testing. B3. The facility personnel acknowledged that the laboratory failed to follow their established policy and provide documentation of accuracy verification procedures as indicated above.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on review of the laboratory's microscope maintenance policy, the microscope maintenance log and interview with the facility personnel, the laboratory failed to document the routine maintenance of the microscope used in patient testing under the sub-specialty of Histopathology. Findings include: 1. There were no entries on the log sheet after June 2018 for the routine maintenance of the microscope which includes weekly cleaning of the microscope stage and ocular eyepieces and grounding check, per laboratory policy. 2. The facility personnel acknowledged that the microscope maintenance was not documented since June 2018. 3. The laboratory's annual test volume in the sub-specialty of histopathology is 504.
D5607	HISTOPATHOLOGY CFR(s): 493.1273(d)(f) (d) Tissue pathology reports must be signed by an individual qualified as specified in paragraph (b) or, as appropriate, paragraph (c) of this section. If a computer report is generated with an electronic signature, it must be authorized by the individual who performed the examination and made the diagnosis. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of patient test reports and interview with the facility personnel, the laboratory failed to have one pathology report signed by the individual who performed the examination and made the diagnosis. Findings include: 1. The laboratory performs patient testing under the sub-specialty of Histopathology, with an approximate annual test volume of 504. 2. Review of the biopsy test report for patient 18-066 on 01/15 /2018 failed to include the signature of the individual making the diagnosis. 3. The facility personnel confirmed that the pathology report indicated above was not signed by the individual who performed the examination and made the diagnosis.