

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D1098554	(X3) Date Survey Completed 11/14/2018
Name of Provider or Supplier Integrated Dermatology Of Yuma	Street Address, City, State 2500 S 8th Ave Ste 101, Yuma, 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
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory manual presented during the survey and interview with the facility personnel, the laboratory failed to have a procedure manual that was approved, signed, and dated by the current laboratory director. Findings include: 1. The laboratory's procedure manual presented for review during the survey conducted on November 14, 2018 failed to include the approval, signature and date of the laboratory director. 2. The facility personnel acknowledged that the procedure manual was not signed and dated by the laboratory director at the time of the survey.</p>
D5433	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on lack of a microscope maintenance policy and interview with the facility personnel, the laboratory failed to have a microscope maintenance policy that</p>

indicates specific routine maintenance procedures as well as scheduled preventative maintenance procedures. Findings include: 1. The policy and procedure manual presented for review during the survey did not contain any policies with regards to microscope maintenance. 2. The facility personnel acknowledged that there were no microscope maintenance policies contained in the manual. 3. The laboratory's annual test volume under the sub-specialty of Histopathology is approximately 500.