

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D2122522	(X3) Date Survey Completed 01/25/2018
Name of Provider or Supplier Hamblin Dermatology Pllc	Street Address, City, State 2291 W 16th St, Safford, 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 January 25, 2018 failed to include the approval, signature and date of the laboratory director. The laboratory began patient testing on January 5, 2017. 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>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's room temperature logs and interview with the</p>

facility personnel, the laboratory failed to define the criteria for the room temperature. Findings include: 1. The laboratory performs Mohs surgery slide interpretation with an annual test volume of approximately 300. The laboratory began patient testing on January 5, 2017. 2. The laboratory documented the room temperature where the staining reagents are stored and utilized for Mohs slide processing, but there was no policy or indication that a room temperature range had been established. 3. The facility personnel confirmed that the laboratory had not established a room temperature range.

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 and Cryostat maintenance policy and interview with the facility personnel, the laboratory failed to indicate the frequency of specific routine maintenance activities. Findings include: 1. The laboratory's established policy titled, "Equipment Quality Control for Microscopes" failed to specify the frequency of the maintenance activities listed in the procedure, including cleaning the stage and ocular eye pieces and performing a grounding check. The procedure also failed to indicate the laboratory's specific protocol for dealing with a nonfunctioning microscope. 2. The laboratory's established policy titled, "Equipment Quality Control for Cryostats" failed to specify the frequency of the maintenance activities listed in the procedure, including cleaning, defrosting, checking the thermometer and performing preventative maintenance and grounding checks. The procedure also failed to indicate the frequency of how often to check the cryostat for proper functioning in laboratory's protocol for dealing with a nonfunctioning microscope. 3. The facility personnel acknowledged that the maintenance procedures indicated above failed to include specific information regarding the frequency of maintenance activities. 4. The microscope and cryostat are used to read and process patient specimens for Mohs testing.