

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2141328	(X3) Date Survey Completed 01/16/2018
Name of Provider or Supplier Dermatology Group Of Florida Pa	Street Address, City, State 1001 Nw 13th St Ste 100, Boca Raton, FL	
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
D3011	<p>FACILITIES CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p> <p>This STANDARD is not met as evidenced by: Based on observation and interview with the laboratory personnel drinking water bottle and cups were kept in the laboratory cabinet along with other laboratory supplies. The findings include: During the laboratory tour on January 16, 2018 at 4 PM, surveyor observed drinking water bottle and cups in the laboratory cabinet along with other laboratory supplies. During an interview on January 16, 2018 at 4 Pm, testing personnel confirmed the above findings.</p>
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the testing person laboratory failed to include the MOHS MAP- a pictorial representation of the pathology report in the MOHS procedure. The findings include: During the record review of Policy and</p>

	<p>Procedure Manual on January 16, 2018 at 5PM, surveyor observed that "MOHS MAP -a pictorial representation of the pathology report" was not included as part of the MOHS surgery procedure for Histopathology Subspecialty "the procedure manual". The testing person confirmed at 5:30 PM on January 16, 2018 that MOHS MAP was not included as part of the MOHS surgery procedure "the procedure manual".</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the testing person laboratory failed to include the MOHS MAP- a pictorial representation of the pathology report in the MOHS procedure. The findings include: During the record review of Policy and Procedure Manual on January 16, 2018 at 5PM, surveyor observed that "MOHS MAP -a pictorial representation of the pathology report" was not included as part of the MOHS surgery procedure for Histopathology Subspecialty "the procedure manual". The testing person confirmed at 5:30 PM on January 16, 2018 that MOHS MAP was not included as part of the MOHS surgery procedure "the procedure manual".</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 the observation and interview with the testing person, the laboratory failed to have the room temperature/ humidity check device. The findings include: On January 16, 2018 at 4PM, surveyor did not observe the room temperature/ humidity check device during the laboratory tour. An interview with the testing person on January 16,2018 at 5:30 PM confirmed that the laboratory did not have the room temperature/ humidity check device.</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>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.</p>

This STANDARD is not met as evidenced by:

Based on observation and interview the MOHS Surgery marking ink bottles were not capped. The findings include: On January 16, 2018 at 3:30PM, surveyor observed two MOHS Surgery marking ink bottles during the laboratory tour; 1) bottle #1 had gauze to keep it closed and 2) bottle # 2 was not capped. Testing personnel did not provide package insert for that. During an interview on January 16, 2018 at 4 PM, testing personnel confirmed the above findings.