

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0927895	(X3) Date Survey Completed 04/04/2019
Name of Provider or Supplier Skin Cancer Treatment Center	Street Address, City, State 10001 Pines Blvd, Pembroke Pines, 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
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 record review and interview with the laboratory director, the laboratory failed to document the room humidity for 2 out of 2 years reviewed. Findings include: Review of the cryostat manual Leica CM1510 indicated a requirement for room humidity not above 60 %. Quality control records of histopathology room revealed that: there was no documentation of the humidity during 2017 and 2018. During an interview on 04/04/19 at 11:00 a.m., the laboratory director confirmed that there was no record of room humidity for the years of reference.</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> <p>This STANDARD is not met as evidenced by: Based on observation and interview with laboratory director, the laboratory had</p>

expired reagents in the cabinet. Findings include: During tour of the laboratory at approximately 10:30 AM on 04/04/2019 the surveyor found: a) Half full bottle of Eosin working solution lot #D238-03 expired 8/27/2016 b) Half full bottle of Hematoxylin Gill 3 lot# 050458 expired 5/2018 c) Partial used Wright Giemsa Stain lot #2269 expired 5/2014 During an interview on 4/4/2019 at 11:30 AM, with the laboratory director, she confirmed the existence of the expired reagents in the cabinet.

D5429

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:
Based on record review and interview with laboratory director, the laboratory failed to perform annual preventive maintenance to microscope and cryostat for 1 out of 2 years reviewed. Findings include: Review of annual maintenance records showed no records of annual preventive maintenance for microscope and cryostat during 2018. During an interview on 4/4/2019 at 11:30 AM, with the laboratory director, she confirmed that there is no documentation that the laboratory performed the annual preventive maintenance for microscope and cryostat during 2018