

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0676451	(X3) Date Survey Completed 07/17/2018
Name of Provider or Supplier Dermatology Associates Of Oak Ridge	Street Address, City, State 599 Oak Ridge Turnpike, Oak Ridge, TN	
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 the observation of a container of instant coffee in laboratory flame cabinet during tour at approximately 8:30 a.m. July 17, 2018, lack of safety protocol for the laboratory and an interview with the Laboratory Manager and Lead Processor, determined the laboratory lacks safety procedures to ensure personnel protection from biohazardous materials. The findings include: 1. Observation of a container of instant coffee in laboratory flame cabinet at approximately 8:30 a.m. July 17, 2018 during tour. 2. Lack of safety protocol for the laboratory to ensure personnel protection from biohazardous materials. 3. An interview with the Laboratory Manager and Lead Processor at approximately 11:30 a.m. July 17, 2018 confirmed there was a container of instant coffee in laboratory flame cabinet and there is no safety protocol for the laboratory to ensure personnel protection from biohazard materials. =====</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</p>

specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:

===== Based on laboratory's maintenance policy for the cryostats, lack of preventive maintenance documentation for cryostat number one and interview with the laboratory manager and lead processor, determined the laboratory failed to have preventive maintenance done on cryostat number one since 2016. The findings include: 1. The Laboratory's maintenance policy for the cryostats state that PM (preventative maintenance) is to be performed every 6 months. 3. Lack of PM documentation since 2016 for cryostat number one. 4. Interview with the laboratory manager and lead processor at approximately 11:30 a.m. July 17, 2018 confirmed there were no PM's performed on cryostat number one for the last two years. =====

D6010

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(2)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(2) Ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed.

This STANDARD is not met as evidenced by:

===== Based on observation around 8:30 a. m. July 17, 2018 (during lab tour) of a container of instant coffee stored in flame cabinet, and interview with the laboratory manager and lead processor, determined the laboratory director failed to ensure a procedure that prohibits anything other than chemicals and reagents be stored in the laboratory flame cabinet. The findings include: 1. Observed around 8:30 a.m. July 17, 2018 a container of instant coffee stored in laboratory flame cabinet with chemicals considered to be hazardous materials. 2. An interview at approximately 11:30 a.m. July 17, 2018 with the laboratory manager and lead processor confirmed the laboratory director failed to ensure a procedure that prohibits anything other than chemicals and reagents be stored in the laboratory flame cabinet. =====

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

===== Based on lack of documented competency for 3 of 3 testing personnel performing KOH (potassium hydroxide testing), Wet Preps and Tzanck Smears and upon interview with the laboratory manager, determined the technical consultant failed to ensure documented annual competencies for 3 testing personnel since 2016. The findings include: 1. There were

no competencies documented for 3 of 3 testing personnel performing KOH, Wet Preps and Tzanck Smears since 2016. 2. An interview with the laboratory manager at approximately 11:30 a.m. July 17, 2018, confirmed the Technical Consultants failed to document annual competencies for 3 of 3 testing persons since 2016 performing KOH, Wet Preps and Tzanck Smears. =====