

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2151836	(X3) Date Survey Completed 05/22/2019
Name of Provider or Supplier Concierge Dermatology & Skin Surgery Center	Street Address, City, State 18341 U S Highway 41, L' Anse, MI	
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, procedure review, and interview with the office manager, the laboratory failed to keep food and beverages out of the laboratory. Findings include: 1. An observation by the surveyor during the laboratory tour on 5/22/19 at 1:13 pm revealed a box with bagged snacks and juice near the cryostat in the laboratory. 2. A review of the laboratory's "General Laboratory Cleaning and Safety" procedure revealed a section stating, "No food, drink, or cosmetics are allowed in the laboratory." 3. An interview with the office manager on 5/22/19 at 1:13 pm confirmed food and beverage were present in the laboratory.</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 observation, procedure review, and interview with the office manager, the laboratory failed to follow written procedures for the manual staining process for 7 (November 2018 to May 2019) of 7 months. Findings include: 1. An observation by</p>

the surveyor during the laboratory tour on 5/22/19 at 1:13 pm revealed a sheet of paper titled, "Manual Staining Process" with staining instructions by the manual staining station. 2. A review of the laboratory's "Staining H&E Frozen Sections By Hand" procedure revealed discrepancies between the policy and the "Manual Staining Process" guide near the manual staining station. Differences include: a. Water dip rinse 1. Manual Staining Process states "10 dips" 2. Procedure states "10-15 dips" b. Acid Wash 1. Manual Staining Process states "15 dips" 2. Procedure states "15 seconds" c. 100% Alcohol 1. Manual Staining Process states "45 seconds" 2. Procedure states "30 seconds" d. Xylene Substitute 1. The Manual Staining Process has three separate steps: the first for 30 seconds, and the last two each for 15 seconds. 2. The procedure has two steps: Xylene for 30 seconds and the holding tank. 3. During the interview on 5/22/19 at 2:03 pm, the office manager confirmed the two staining procedures contained discrepancies.

D5415

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(c)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:
. Based on observation and interview with office manager, the laboratory failed to label the inking reagents used for specimen grossing with the expiration dates for the current lots in use. Findings include: 1. An observation by the surveyor during the laboratory tour on 5/22/19 at 1:13 pm revealed aliquoted inking reagents without expiration dates affixed on the storage containers. 2. A review of the laboratory's "Preparation and Labeling" procedure revealed a section stating, "All reagents are to be labeled with the following information: reagent, dilution, date of preparation, date received and opened, technician, and temperature for storage (if not room temperature)." 3. During the interview on 5/22/19 at 1:13 pm, the office manager confirmed the inking reagents were missing expiration dates on the storage containers.