

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2158109	(X3) Date Survey Completed 08/20/2019
Name of Provider or Supplier Concierge Dermatology & Skin Surgery	Street Address, City, State 1500 Sand Point Road, Munising, 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
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: . Based on observation and interview with office manager, the laboratory failed to label 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 8/20/19 at 9:07 am 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 (if any), date of preparation, date received and opened, technician (initials), and temperature for storage (if not room temperature)." 3. During the interview on 8/20/19 at 9:07 am, the office manager confirmed the inking reagents were missing expiration dates on the storage containers.</p>