

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  52D1104619	<b>(X3) Date Survey Completed</b>  01/18/2022
<b>Name of Provider or Supplier</b>  Fleming Dermatopathology	<b>Street Address, City, State</b>  4324 W Bradley Road, Brown Deer, WI	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5413</b>	<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 surveyor observation of laboratory records and reagent storage and interview with the general supervisor, the laboratory did not define criteria consistent with the manufacturer's instructions for refrigerator storage of histology reagents. Findings include: 1. Direct observation of the "Daily Temperatures" log on January 18, 2022 at 2:50 PM showed the laboratory defined acceptable temperature range for the laboratory "Refrigerator/Freezer" is "2 C and 4 C +/-5". 2. Observation of the reagents in the laboratory refrigerator on January 18, 2022 at 2:52 PM revealed the following reagents with the manufacturer's acceptable storage range of two to eight degrees Celsius: a. Warp Red Chromogenic Kit, Lot 040521 b. PRAME, Lot 042121A c. Background Punisher, Lot 100121A d. Antihuman IgA, Lot 20073154 e. Antihuman IgG, Lot 20073915 f. Antihuman IgM, Lot 20085091 g. Antihuman C3, Lot 41250760 h. Fibrinogen, Lot 41288732 i. Fluorescence Antibody Diluent, Lot 81221A-2 3. Interview with the general supervisor on January 18, 2022 at 3:00 PM confirmed the laboratory's defined range for acceptable storage of histology reagents was not consistent with the manufacturer's instructions.</p>