

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D0451899	(X3) Date Survey Completed 08/10/2022
Name of Provider or Supplier Hillside Medical Office	Street Address, City, State 855 N Hillside, Wichita, KS	
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 review of the manufacturer's package insert instructions, freezer temperature logs for the time period of 7/22/22 - 8/10/22, and interview, the laboratory failed to store quality control (QC) materials under conditions consistent with the manufacturer's instructions in one of one freezers for 10 days out of 20 days. Findings: 1. Review of the Bio-Rad Liquichek Immunology Control package insert and the Bio-Rad Liquid Assayed Multiquel package insert indicated that the storage temperature range was -20 degrees Centigrade to -70 degrees Centigrade for both QC materials. These materials were first received on 7/22/22 and stored in the lab freezer. 2. Review of the "HILLSIDE MEDICAL OFFICE MAINTENANCE/QC LOG" for the temperature readings on "Lab Freezer" from 7/22/22 to 8/10/22 revealed: a. Temperatures were out of the controls' required range (-20 degrees Centigrade to -70 degrees Centigrade) for 10 days out of 20 days recorded. No temperature readings were recorded on weekend days when the facility is closed. This accounted for 6 days of the 20 day storage period. b. The "HILLSIDE MEDICAL OFFICE MAINTENANCE/QC LOG" was not updated to correct the temperature requirements of the new QC material and still listed an acceptable range of "(Less than -18 C)" 3.</p>

Interview with the testing personnel #1 on 8/10/22 at 9:30 a.m. confirmed the laboratory failed to store QC materials under conditions consistent with the manufacturer's instructions in one of one freezers for 10 days out of 20 days.