

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0466485	(X3) Date Survey Completed 03/22/2022
Name of Provider or Supplier St Vincent Morrilton Rural Health Clinic	Street Address, City, State 1711 East Harding, Morrilton, AR	
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: Through observation, review of temperature records, lack of documentation and interview it was determined that the laboratory failed to monitor the temperature of one of two refrigerators in which reagents with storage temperature requirements were stored on each day of operation. Findings follow: A) During a tour of the laboratory on 3/22/22 at 09:15 AM two refrigerators containing items with a refrigerated temperature storage requirement were observed. B) During a review of the laboratory's temperature records it was noted that temperature records for only one refrigerator were presented. C) During a tour of the laboratory on 3/22/22 at 11:15 AM, nine boxes of Abbott Afinion Hemoglobin A1C lot # 10214933 expiration date 2023-11-15 with a storage temperature requirement of 2 to 8 degrees C. were observed in one of two refrigerators present in the laboratory. D) Upon request, the laboratory could not present the temperature records for the refrigerator in which the reagents identified above were stored,. E) In an interview on 3/22/22 at 11:15 AM the laboratory staff member, identified as number four on the CMS 209 form, stated that the daily temperature of the refrigerator in which the Afinion reagents were stored had not been monitored and recorded..</p>