

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 35D0041814	(X3) Date Survey Completed 01/19/2021
Name of Provider or Supplier Smp Health St Aloisius	Street Address, City, State 325 Brewster St E, Harvey, ND	
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 observation, manufacturer's instructions review, record review, and staff interview, the laboratory failed to store BioRad chemistry controls in the Crosley freezer according to the manufacturer's instructions on 38 of 50 days from December 1, 2020 through January 19, 2021 (12/03, 12/05 - 12/31, 01/21, 01/05 - 01/07, 01/11, 01/14 - 01/16, 01/18, and 01/19). Findings include: 1. Observation of the Crosley freezer occurred at 3:50 p.m. on 01/19/21. This freezer contained the following BioRad Liquichek chemistry controls: 9 vials Specialty Immunoassay, 11 vials Immunology, and 86 vials Immunoassay Plus. 2. Reviewed at 3:50 p.m. on 01/19/21, the manufacturer's labels on the BioRad Liquichek chemistry controls stated to store at -20 to -70 degrees Celsius. 3. Review of the December 1, 2020 through January 19, 2021 Crosley freezer temperature records occurred at 4:10 p.m. on 01/19/21. These records showed the temperature of the Crosley freezer was warmer than -20 degrees Celsius for the following 38 days from December 1, 2020 through January 19, 2021: 12/03, 12/05 - 12/31, 01/21, 01/05 - 01/07, 01/11, 01/14 - 01/16, 01/18, and 01/19). 4. During interview at 4:30 p.m. on 01/19/21, a technical supervisor (#1) confirmed the Crosley freezer had not been at the proper temperature for storage of the BioRad chemistry controls all days from December 1, 2020 through January 19, 2021.</p>