

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D2153799	(X3) Date Survey Completed 09/09/2026
Name of Provider or Supplier St Bernards Physician Clinics, Inc	Street Address, City, State 1312 1st Street, Kennett, MO	
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	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) 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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on observation of the freezer during the laboratory tour, review of the Abbott i-STAT high sensitivity troponin (hs-Tnl) control package insert, January 2026 to date September 9, 2026 laboratory temperature logs, and patient results and interview with the technical consultant (TC) #1, the laboratory failed to ensure the freezer temperature was maintained as required by the manufacturer for 39 of 252 days. Findings: 1. Observation of the freezer during the laboratory tour showed 1 box of Abbott i-STAT hs-Tnl control level 1 Lot # 551199 exp 07/31/2027 and 1 box of Abbott i-STAT hs-Tnl control level 3 Lot # 571199 exp 07/31/2027 in use. 2. Review of the Abbott i-STAT hs-Tnl control package insert states "Store frozen at less than or equal to -20 degrees Celsius (-4 degrees Fahrenheit) until the expiration date printed on the box and vial labels". 3. Review of laboratory temperature logs showed "lab freezer temperature range less than or equal to -15 degrees Celsius". 4. Review of the laboratory temperature logs showed freezer temperature was not maintained as required by the manufacturer for 39 of 252 days. 5. Review of patient results showed the laboratory performs approximately 112 hs-Tnl patient tests per year. 6. Interview

with the TC #1 on September 9, 2026 at 10:30 AM confirmed the laboratory failed to ensure the freezer temperature was maintained as required by the manufacturer for 39 days.