Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D0989496	01/12/2022
Name of Provider or Supplier	**Street Address, City, State**	
Sterling Urgent Care	740 S Woodruff Ave, Idaho Falls, ID	

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
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on a random review of temperature logs and an interview with the laboratory manager on 1/12/2022, the laboratory failed to document corrective actions when sample and reagent storage temperatures were outside of the established ranges for the refrigerator and freezer. The findings include: 1. A random review of laboratory temperature logs identified that the laboratory failed to document corrective actions for the refrigerator used to store patient samples when it was not within the established range of 2-8 C for six (6) of 30 days in March 2021 and nine (9) of 29 days in February 2021. 2. A random review of laboratory temperature logs identified that the laboratory failed to document corrective actions for the freezer used to store patient samples and reagents when it was not within the established range of less than or equal to -20 C for six (6) of 30 days in March 2021 and one (1) of 29 days in February 2021. 3. An interview with the laboratory manager on 1/12/2022 at 3:10 pm confirmed that the laboratory had not documented corrective actions for all out of range temperatures. 4. The laboratory reports performing 5,400 tests annually.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory

	director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on a record review of the Sysmex PocHi verification and an interview with the laboratory manager on 1/12/2022, the laboratory director failed to ensure that the verification was adequate. The findings include: 1. A record review of the new instrument verification of the Sysmex PocHi, used for hematology testing, identified that the laboratory director failed to review and approve the verification results for accuracy, precision, reportable range and carryover before beginning patient testing on 6/12/2021. 2. An interview with the laboratory manager on 1/12/2022 at 2:50 pm confirmed that the laboratory director failed to review and approve the verification of the Sysmex PocHi. 3. The laboratory reports performing 2000 hematology tests annually.