Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D2157719	12/01/2021
Name of Provider or Supplier	**Street Address, City, State**	
Sterling Urgent Care	507 S Main Street, Hailey, 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
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on review proficiency testing (PT) records from American Proficiency Institute (API) and an interview with the laboratory manager on 12/1/2021 the laboratory failed to evaluate the accuracy of testosterone that was assigned an artificial score of 100% because it was ungraded by the PT provider. The findings include: 1. A review of chemistry core 2021 event 2 records from API identified one (1) testosterone sample, IA-07, that was ungraded due to lack of consensus, and was given an artificial score of 100%. The laboratory failed to evaluate the accuracy of the result for testosterone sample IA-07. 2. An interview with the laboratory manager on 12/1/2021 at 2:57 pm confirmed that the laboratory failed to evaluate the accuracy of the ungraded PT result for testosterone that was given an artificial score of 100%. 3. The laboratory reports performing 300 endocrinology tests annually.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

	This STANDARD is not met as evidenced by: Based on a direct observation and an interview with the laboratory manger on 12/1 /2021, the laboratory failed to discontinue the use of 11 expired specimen collection tubes. The findings include: 1. During the laboratory tour on 12/1/2021 a direct observation of specimen collection tubes identified that the laboratory failed to discontinue the use of eight (8) BD sodium heparin tubes, lot 0167227, expiration 10 /31/2021 and three (3) BD lithium heparin tubes, lot 0316490, expiration 11/30/2021 used for complete metabolic testing on the Piccolo and for send out testing. 2. An interview with the laboratory manager on 12/1/2021 at 4:10 pm confirmed the above finding.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on a direct observation, record review and an interview with the laboratory manger on 12/1/2021, the laboratory failed to calibrate pipettes used for endocrinology testing. The findings include: 1. During the laboratory tour on 12/1 /2021 a direct observation of two (2) NanoEntek Frend system adjustable pipettes identified that the laboratory failed to calibrate the two (2) pipettes used to perform endocrinology testing on the Frend. 2. A review of available laboratory records identified that the laboratory failed to have documentation of pipette calibrations. 3. An interview with the laboratory manager on 12/1/2021 at 4:20 pm confirmed that the laboratory had no documentation of calibration for the two (2) pipettes. 4. The laboratory reports performing 300 endocrinology tests.