Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D2275110	11/13/2023
Name of Provider or Supplier	**Street Address, City, State**	
Sterling Urgent Care	900 Highway 41 Ste 2 & 3, Post 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
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions for use (IFU), a direct observation and an interview with he laboratory supervisor on 11/13/2023, the laboratory failed to follow the IFU for specimen processing for testing on the NanoEntek frend. The findings include: 1. A review of NanoEntek frend IFUs for testosterone, prostate specific antigen (PSA), thyroid stimulating hormone (TSH) and free thyroxine (FT4) identified that samples are to be centrifuged for 10 minutes at 3,000 RPM. 2. A direct observation of the centrifuge preventive maintenance (PM) label from 2/8/2023 identified that the fixed time and speed centrifuge ran at 3292 RPM for 15 minutes. 3. A review of the testing IFUs and the direct observation of centrifuge PM documents identified that the laboratory failed to follow the manufacturer's specimen centrifuge time for PSA, TSH, FT4 and testosterone testing. 4. An interview with the laboratory supervisor on 11/13/2023 at 3:05 pm confirmed that they were not centrifuging samples for the correct length of time. 5. The laboratory reports performing 300 tests annually on the NanoEntek frend.
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 supervisor on 11/13/2023, the laboratory failed to discontinue the use of expired collection and transport devices. The findings include: 1. During the laboratory tour on 11/13/2023 a direct observation identified that the laboratory failed to discontinue the use of three expired BD Affirm ambient temperature transport system kits lot BO1E257M expiration 10/31/2023 and three expired Aptima unisex swab specimen collection kits lot 330850 expiration 6/3/2023. 2. An interview with the laboratory supervisor on 11/13/2023 at 2:55 pm confirmed the above findings.