Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D0989496	09/11/2019
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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on a record review of proficiency testing and an interview with the laboratory lead, the laboratory failed to test the American Association of Bioanalysts (AAB) and American Proficiency Institute (API) proficiency testing (PT) samples in the same manner as patient testing since the last survey on December 7, 2017. This is a repeat deficiency. Findings: 1. A record review of all AAB and API PT events for 2018 and 2019 revealed that one (1) of seven (7) testing personnel performed the PT testing for all events. 2. An interview on September 11, 2019 at approximately 2:20 P.M., with the laboratory lead, confirmed the laboratory did not rotate the PT samples among all testing personnel in 2018 and 2019.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory lead, the laboratory failed to verify the accuracy for prostate specific antigen (PSA) and testosterone at least twice annually since the last survey on December 7, 2017. Findings: 1. A record review revealed no documentation of verification of accuracy for PSA and

	testosterone since the time of the last survey on December 7, 2017. 2. The laboratory performed approximately 100 PSA tests and 100 testosterone tests in 2018. 3. An interview on September 11, 2019 at approximately 2:20 PM, with the laboratory lead, confirmed the laboratory failed to verify the accuracy of PSA and testosterone performance at least twice annually.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory lead, the laboratory failed to follow their approved critical value policy. Findings: 1. A record review of polices and patient test reports revealed the laboratory failed to follow the approved critical value reporting procedure to document when critical values are reported to a provider. 2. An interview on September 11, 2019 at approximately 1:25 P.M., with the laboratory lead, confirmed that the laboratory failed to follow the critical value policy.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: (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. This STANDARD is not met as evidenced by: Based on an observation of frozen control material, a review of freezer temperature records and an interview with the laboratory lead, the laboratory failed to define the correct acceptable range for endocrinology control storage. Findings: 1. An observation of the lab freezer on September 11, 2019 at approximately 3:45 P.M. revealed the storage of 4 boxes of endocrinology controls, with a manufacturer's storage requirement of -20 degrees Celcius or colder. 2. A review of temperature logs for the freezer revealed an acceptable temperature range of -15 degrees Celsius or colder. 3. An interview on September 11, 2019 at approximately 3:45 P.M., with the laboraotry lead, confirmed that that the laboratory failed to establish an acceptable range for endocrinology control storage.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

	This CONDITION is not met as evidenced by: Based on a record review and an interview with the laboratory lead, the laboratory failed to provide a technical consultant who meets the qualifications and provide technical oversight for the laboratory. Refer to D6035
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory lead, the laboratory failed to provide a qualified technical consultant for the position based on education, training, and experience requirements. Findings: 1. A review of the CMS 209 Personnel Report form for the laboratory revealed the position for a qualified technical consultant was not met. 2. An interview on September 11, 2019 at approximately 1:15 P.M. with the laboratory lead, revealed the laboratory appointed a new laboratory director in May 2019 who does not have at least one year of documented laboratory training or experience in the specialties of Hematology and Endocrinology.