Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	53D2184485	01/23/2023
Name of Provider or Supplier	**Street Address, City, State**	
Sterling Urgent Care	1952 Harrison Drive, Suite #1, Evanston, WY	

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 review of proficiency testing (PT) records, the CMS (Centers for Medicare and Medicaid Services) 209 Laboratory Personnel Report, and personnel records, and staff interview, the laboratory failed to rotate testing personnel performing API (American Proficiency Institute) endocrinology and hematology PT for 8 of 8 proficiency testing events reviewed from September 2021 through December 2022. The findings were: 1. Review of the 8 API proficiency testing events performed from September 2021 through December 2022 showed no evidence TP #1 had been included. 2. Review of the CMS 209 Laboratory Personnel Report, dated 1/14/23, showed testing personnel (TP) #1 was listed as performing moderate complexity testing. Review of the personnel records for TP #1 showed an initial competency assessment had been completed on 9/2/21. Interview with TP #1 on 1/23/23 at 3:59 PM revealed she had not been included in the proficiency testing rotation. 3. Interview with the laboratory manager on 1/23/23 at 4 PM confirmed TP #1 had not participated in the proficiency testing events.
D5020	ENDOCRINOLOGY CFR(s): 493.1212 If the laboratory provides services in the subspecialty of Endocrinology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299.

	This CONDITION is not met as evidenced by: Based on observation, review of the laboratory's quality control (QC) records, individualized quality control plan (IQCP), and patient testing log, and staff interview, the laboratory failed to ensure QC was performed and was acceptable prior to testing patient samples for 2 consecutive survey cycles; 9/7/21 and 1/23/23 (D5461).
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of proficiency testing records, lack of documentation, and staff interview, the laboratory failed to review and evaluate proficiency testing results for 2 of 9 testing events from September 2021 through December 2022. The findings were: 1. Review of the American Proficiency Institute (API) proficiency testing (PT) report failed to include documentation the laboratory had evaluated test scores of less than 100%. The following concerns were identified: a. Review of the 2021 API hematology event #3 PT results showed the laboratory scored an 80% on MCV (mean corpuscular volume) and the lymphocyte count. There was no documentation the laboratory had investigated the reason for the 80% score. b. Review of the 2022 API hematology event #2 showed the laboratory scored an 80% on hemoglobin. There was no documentation the laboratory had investigated the reason for the 80% score. 2. Interview with the laboratory manager on 1/23/23 at 3:52 PM confirmed the laboratory had failed to evaluate the reason for the 80% scores on the proficiency testing events.
D5461	CONTROL PROCEDURES CFR(s): 493.1256(d)(6)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Perform control material testing as specified in this paragraph before resuming patient testing when a complete change of reagents is introduced; major preventive maintenance is performed; or any critical part that may influence test performance is replaced. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation, review of the laboratory's quality control (QC) records, individualized quality control plan (IQCP), and patient testing log, and staff interview, the laboratory failed to ensure QC was performed and was acceptable prior to testing and reporting patient results for 1 of 4 analytes (PSA) performed on the FREND immunoassay analyzer. The laboratory performed approximately 50 PSA patient tests per year. The findings were: 1. Review of the laboratory's QC records showed QC was performed on PSA (prostate-specific antigen) lot #301022 on 9/23/22 and level one had failed. A note on the QC log sheet stated "No patients ran til control out of range resolved." There was no evidence the failed QC was resolved or QC had been performed on lot #301022 following the 9/23/22 failure. 2. Review of the patient testing log showed 3 patient tests, using PSA lot #301022, were performed and

	reported; patient #1 on 12/7/22, patient #2 on 12/13/22, and patient #3 on 1/10/23. 3. Observation of the laboratory's reagent storage refrigerator on 1/23/23 at 5:15 PM showed two unopened PSA lot #301022 reagent packages were intermingled in a box with PSA lot #301025. 4. Review of the FREND analyzer IQCP, last reviewed by the laboratory director on 4/4/22, showed QC will be performed monthly, with the change in test lots, or with each new shipment, whichever comes first. 5. Interview with the laboratory director and TP #1 on 1/23/23 at 5:30 PM confirmed PSA lot #301022 should not have been used for patient testing. THIS IS A REPEAT DEFICIENCY, last cited on 9/7/21.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of personnel files, review of the CMS (Centers for Medicare and Medicaid Services) 209 Laboratory Personnel Report, lack of documentation, and staff interview, the technical consultant failed to complete a competency assessment for 1 of 1 testing personnel (TP #1) after one year of performing patient testing. The findings were: 1. Review of the personnel file for TP #1 showed a date of hire of July 2021, an initial competency assessment was completed on 9/2/21, and a 6-month competency assessment was completed on 4/4/22. There was no evidence a competency assessment had been completed after TP #1 had performed one year of patient testing. 2. Interview with the laboratory manager on 1/23/23 at 4 PM confirmed the competency assessment had not been completed.