Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	53D2184485	09/07/2021
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
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on record review and staff interview, the laboratory failed to report 97 of 97 SARS-CoV-2 patient test results, as required, for 25 weeks of testing (3/13/21 to 9/7/21) reviewed. The findings were: 1. Review of the laboratory's documentation showed 97 SARS-CoV-2 patient tests had been performed using the Access CareStart test system since 3/13/21. There was no evidence the test results had been reported to the State Public Health Laboratory. 2. Interview with testing personnel #1 on 9/7/21 at 4:50 PM confirmed the negative SARS-CoV-2 patient test results had not been reported to the State Public Health Laboratory. In addition, testing personnel #1 stated the positive SARS-CoV-2 patient test results had been reported, however the laboratory was unable to verify the positive results had been transmitted to the State Public Health Laboratory.
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 lack of documentation and staff interview, the laboratory failed to have a written procedure for reporting SARS-CoV-2 positive and negative test results. The findings were: 1. Review of the laboratory's procedures showed no evidence a policy and procedure had been developed in regard to reporting SARS-CoV-2 positive and negative test results to the appropriate agencies. 2. Interview with testing personnel #1 on 9/7/21 at 4:55 PM confirmed the laboratory did not have a written procedure for reporting SARS-CoV-2 test results.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on quality control (QC) record review, review of the patient testing log, and staff interview, the laboratory failed to perform QC which included a positive and negative control material each day of testing from 6/3/21 to 9/4/21 for the Healgen COVID-19 IgG and IgM antibody test system. This failure affected 10 patient samples. The findings were: 1. Review of the laboratory's QC records showed the laboratory performed a positive and negative control for the Healgen COVID-19 IgG and IgM antibody test system on 2/9/21 for lot number 2006120. Review of the patient testing log showed a patient test was performed on 6/3, 3 on 8/25, 2 on 8/30, 3 on 9/4, and 1 on 9/6. There was no documentation a positive and negative control had been run on each day of patient testing. 2. Interview with testing personnel #2 on 9/7 /21 at 3:10 PM confirmed the laboratory had failed to perform a positive and negative control each day of patient testing.
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 quality control (QC) record review, review of the FREND immunoassay instrument instructions for use (IFU), review of the patient testing log, review of the laboratory's individualized quality control plan (IQCP), and staff interview, the

	laboratory failed to perform QC with every new lot number or shipment of testing cartridges. The laboratory performed 40 TSH (thyroid stimulating hormone), 15 PSA (prostate-specific antigen), 6 testosterone, and 6 FT4 (free thryroxine) tests from 2/18 /21 to 9/7/21. The findings were: 1. Review of the QC records showed the following concerns: a. On 3/31/21 a low level of QC was performed on PSA lot #309051 and a high level of QC was performed on PSA lot #309053. On 5/3/21 a low and high level of QC was performed on PSA lot #309053. There was no documentation a low level of QC was performed on PSA lot #309053 before it was used for patient testing. b. On 5/3/21 a low and high level of QC was performed on TSH lot #400006. On 5/30/21 a low and high level of QC was performed on TSH lot #400009. There was no documentation QC was performed on TSH lot #400009 before it was used for patient testing. c. On 5/30/21 a low and high level of QC was performed on FT4 lot #410903. On 7/10/21 a low and high level of QC was performed on FT4 lot #410904. There was no documentation QC was performed on FT4 lot #410904 before it was used for patient testing. d. On 5/30/21 a low and high level of QC was performed on testosterone lot #350003. On 7/10/21 a low and high level of QC was performed on testosterone lot #350009. There was no documentation QC was performed on testosterone lot #35009 before it was used for patient testing. 2. Review of the laboratory's patient testing logs showed 2 PSA tests were performed between 3/31 and 5/3; 4 TSH tests were performed between 5/3 and 5/30 and 3 FT4 tests were performed between 5/30 and 7/10. 3. Review of the laboratory's IQCP showed QC on the FREND analyzer was only to be performed monthly. 4. Review of the FREND System IFU showed "If you comply with IQCP 2016, controls for each assay only need to be run on the FREND once every 30 days, every new shipment of cartridges, or every new lot number of cartridges..." 5. Interview with testing personnel #1 on 9/7 /21 at 3:20 PM confirmed QC had not been performed with each new lot number or shipment of the FREND testing cartridges before patient testing.