Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	53D2147193	01/26/2022
Name of Provider or Supplier	**Street Address, City, State**	
Sterling Urgent Care Of Wyoming	47 Doc Perkes Rd, Afton, 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
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (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 patient test records, review of the laboratory's individualized quality control plan (IQCP), and staff interview, the laboratory failed to ensure QC was performed with every new lot number or shipment of TSH (thyroid stimulating hormone) and FT4 (free thyroxine) testing cartridges prior to testing patient samples for 3 of 13 patient test records reviewed between 5/14 /21 and 11/12/21 (26 weeks). The laboratory performed approximately 13 FT4 and 79 TSH patent tests during that timeframe. The findings were: 1. Review of patient #1's laboratory results showed a TSH was performed using lot #401003 on 6/23/21. Review of the "Frend TSH Monthly External QC" record showed no evidence QC had been performed on TSH lot #401003 prior to patient testing or anytime thereafter. Review of the FREND TSH product insert showed each test kit contained 25 cartridges. 2. Review of patient #1's laboratory results showed a FT4 was performed using lot #410904 on 6/23/21. Review of the "Frend FT4 Monthly External QC" record showed QC was performed on FT4 lot #410904 on 6/25/21. There was no evidence QC had been performed on FT4 lot #410904 prior to patient testing. 3. Review of patient #2's laboratory results showed a FT4 was performed using lot

	#410904 on 5/14/21. Review of the Frend FT4 Monthly External QC record showed QC was performed on FT4 lot #410904 on 6/25/21. There was no evidence QC had been performed on FT4 lot #410904 before it was used for patient testing. 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. Review of the FREND IQCP last reviewed by the laboratory director on 12/13/21 showed "...External quality control...the lab performs monthly or with the change in lot #s whichever comes first." 6. Interview with testing personnel #1 on 1/26/22 at 7:15 PM confirmed QC had not been performed with each new lot number or shipment of the FREND testing cartridges prior to being used for patient testing.