

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 53D2147193	<b>(X3) Date Survey Completed</b> 01/31/2024
<b>Name of Provider or Supplier</b> Sterling Urgent Care Of Wyoming	<b>Street Address, City, State</b> 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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5020</b>	<p>ENDOCRINOLOGY CFR(s): 493.1212</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on review of the laboratory's quality control (QC) records, the FREND immunoassay instrument manufacturer's instructions for use, individualized quality control plan, the 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; 1/26/22 and 1/31/24 (D5445).</p>
<b>D5445</b>	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>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.</p> <p>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</p>

laboratory's individualized quality control plan (IQCP), and staff interview, the laboratory failed to ensure QC was performed with every new lot number, every 30 days, or with each new shipment of TSH (thyroid stimulating hormone), FT4 (free thyroxine) and testosterone testing cartridges prior to testing patient samples for 12 of 28 patient test records reviewed between 11/16/23 and 1/27/24 (72 days). This failure affected 9 of 16 patients (#1, #2, #3, #4, #5, #6, #7, #8, #9). The laboratory performed approximately 300 endocrinology patient tests on the FRENDS instrument annually. The findings were: 1. Review of patient #1's laboratory results showed a FT4 was performed using lot #413001 and a testosterone was performed using lot #353004 on 12/6/23. Review of the "Frend FT4 Monthly External QC" record showed QC was last performed on lot #413001 on 7/31/23. Review of the "Frend Testosterone Monthly External QC" record showed no evidence QC had been performed on testosterone lot #353004 prior to patient testing. 2. Review of patient #2's laboratory results showed a testosterone was performed using lot #353004 on 12/6/23. Review of the "Frend Testosterone Monthly External QC" record showed no evidence QC had been performed on testosterone lot #353004 prior to patient testing. 3. Review of patient #3's laboratory results showed a FT4 was performed using lot #413001 on 12/9/23. Review of the "Frend FT4 Monthly External QC" record showed QC was last performed on lot #413001 on 7/31/23. 4. Review of patient #4's laboratory results showed a FT4 was performed using lot #413001 on 12/14/23. Review of the "Frend FT4 Monthly External QC" record showed QC was last performed on lot #413001 on 7/31/23. 5. Review of patient #5's laboratory results showed a FT4 was performed using lot #413001 on 12/14/23. Review of the "Frend FT4 Monthly External QC" record showed QC was last performed on lot #413001 on 7/31/23. 6. Review of patient #6's laboratory results showed a TSH was performed using lot #403014 on 12/29/23. Review of the "Frend TSH Monthly External QC" record showed no evidence QC had been performed on TSH lot #403014 prior to patient testing. 7. Review of patient #7's laboratory results showed a TSH was performed using lot #403014 on 1/19/24. Review of the "Frend TSH Monthly External QC" record showed no evidence QC had been performed on TSH lot #403014 prior to patient testing. 8. Review of patient #8's laboratory results showed a TSH was performed on lot #403014 and a testosterone was performed on lot #353001 on 1/20/24. Review of the "Frend TSH Monthly External QC" record showed no evidence QC had been performed on TSH lot #403014 prior to patient testing. Review of the "Frend Testosterone Monthly External QC" record showed QC was last performed on lot #353001 on 11/17/23. 9. Review of patient #9's laboratory results showed a TSH was performed on lot #403014 and a FT4 was performed using lot #413003 on 1/22/24. Review of the "Frend TSH Monthly External QC" record showed no evidence QC had been performed on TSH lot #403014 prior to patient testing. Review of the "Frend FT4 Monthly External QC" record showed QC was last performed on lot #413003 on 12/18/23. 10. Review of the FRENDS System IFU showed "If you comply with IQCP 2016, controls for each assay only need to be run on the FRENDS once every 30 days, every new shipment of cartridges, or every new lot number of cartridges..." 11. Review of the FRENDS IQCP, last reviewed by the laboratory director on 3/13/23, showed "... External quality control...the lab performs monthly or with the change in test lots, or with each new shipment, whichever comes first..." 12. Interview with testing personnel #1 on 1/31/24 at 12:04 PM confirmed QC had not been performed with each new lot number, every 30 days, or shipment of the FRENDS testing cartridges as required. THIS IS A REPEAT DEFICIENCY, last cited on 1/26/22.

**D5791**

ANALYTIC SYSTEMS QUALITY ASSESSMENT  
CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on review of quality assessment documentation and staff interview, the laboratory failed to have an ongoing system to monitor, assess, and correct problems in the analytic system which assesses quality control (QC). This failure resulted in deficiencies cited at D5445 for two consecutive survey cycles (2022, 2024). The findings were: 1. Review of the laboratory manager's random patient record quality assessment review showed no evidence QC for the subspecialty of endocrinology was monitored to ensure the laboratory's "Individualized Quality Control Plan" was followed. 2. Telephone interview with the laboratory manager on 1/31/24 at 12:04 PM confirmed the quality assessment review did not include monitoring the quality control of the test cartridges used on the FREND analyzer.