

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 53D2147193	(X3) Date Survey Completed 10/24/2019
Name of Provider or Supplier Sterling Urgent Care Of Wyoming	Street Address, City, State 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
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on patient and quality control records review, lack of documentation, and interview with the laboratory manager, the laboratory failed to retain quality control instrument printouts at least two years for complete blood cell counts (CBC), Thyroid Stimulating Hormone (TSH), Free Thyroxine (FT4), Prostate Specific Antigen (PSA), and Testosterone tests for 4 of 8 test days of quality control performance reviewed. The laboratory performs approximately 400 complete blood cell counts per year and 300 TSH, FT4, PSA, and Testosterone tests per year. Findings include: 1. Quality control records for patient test days: 12/04/2018 for patient #051075 for PSA testing; 03/01/2019 for patient #122495 for TSH and FT4 tests; 07/31/2019 for patient #110682 for CBC testing; and 10/11/2019 for patient #60555 for FT4 and TSH tests failed to have quality control performance instrument printouts retained for at least two years. 2. In an interview with staff on 10/24/2019 at approximately 4:15 P.M., the laboratory manager confirmed he could not locate the instrument printouts to verify quality controls were performed and were within their acceptable ranges.</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p>

This STANDARD is not met as evidenced by:
Based on proficiency testing records review, quality assessment records review, lack of documentation, and interview with staff, the laboratory failed to verify prostate specific antigen (PSA) and testosterone testing at least twice annually from May 2018 when testing began to October 2019. The laboratory tests approximately 2 to 4 tests per month. Findings include: 1. Proficiency testing and quality assessment records review failed to include twice annual verification of PSA and testosterone tests accuracy for 2018. 2. In an interview with staff on 10/24/2019 at approximately 4:30 P.M. the laboratory manager stated the laboratory did not verify PSA and testosterone test's accuracy twice annually for 2018.

D5437

CALIBRATION AND CALIBRATION VERIFICATION
CFR(s): 493.1255(a)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:
Based on hematology complete blood cell (CBC) counter calibration records review, lack of documentation, and interview with staff, the laboratory failed to follow the manufacturer's instructions to perform instrument calibration every six months for 1 of 3 six month periods over 18 months of testing reviewed. The laboratory performed approximately 1 to 2 CBC tests per day. Findings include: 1. Calibration records review failed to include a calibration performed between 05/08/2018 and 03/27/2019. 2. The manufacturer provided instructions to calibrate the Poch i 100 cell counting instrument once every six months in the operator's manual and on each calibration work sheet calibration certificate with the next calibration due date. 3. In an interview conducted on 10/24/2019 at approximately 3:45 P.M., the laboratory manager confirmed the laboratory failed to perform a calibration due in November 2018.

D5469

CONTROL PROCEDURES
CFR(s): 493.1256(d)(10)(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-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must

document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on quality control (QC) records review, lack of documentation, and interview with the laboratory manager, the laboratory failed to verify commercial quality control ranges for complete blood cell for approximately 4 lot numbers of hematology controls. The laboratory performed approximately 2 to 5 complete blood cell tests per day. Findings include: 1. Quality control records review failed to include documentation the laboratory verified new lot numbers of Hematology quality control verifying the laboratory could recover values within the manufacturer's stated ranges at the time the controls are placed in use. 2. In an interview with the laboratory manager on 10/24/2019 at approximately 4:00 P.M., the laboratory manager stated the laboratory did not document they verified new lot numbers of complete blood count quality controls ranges were acceptable (within the manufacturer's stated ranges) comparing the new lot number of controls to the stated values when they started new lot numbers.