

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D0453290	(X3) Date Survey Completed 06/21/2018
Name of Provider or Supplier Bob Wilson Memorial Hospital	Street Address, City, State 415 N Main St, Ulysses, KS	
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
D5215	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).</p> <p>This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) proficiency testing (PT) records, three events in 2016 and three events in 2017 and one event in 2018, and confirmed by interview of technical consultant #4 (refer to laboratory personnel report CMS-209) at 09:00 AM on June 21, 2018, the laboratory failed to evaluate ungraded PT scores. The findings include: 1. For API 2016 3rd event Chemistry Group 2, the laboratory received not graded test scores (no consensus) for the following: Sample: CH-13 Free Thyroxine CH-13 TSH 2. For API 2017 1st event Core Chemistry, the laboratory received not graded test scores (no consensus) for the following: Sample: CH-01 Free Thyroxine 3. For API 2017 1st event Core Chemistry, the laboratory received not graded test scores with "see Data Summary" for the following: Sample: CH-01 Triglycerides 4. The laboratory failed to provide documentation at the time of the survey evaluation of the ungraded PT test scores.</p>
D5439	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)</p>

-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:

Based on review of calibration verification records for the D-Dimer Triage Meter and interview with technical consultant #1 (refer to Laboratory Personnel Report CMS-209) at 11:10 on June 21, 2018 revealed the laboratory failed to perform calibration verification due April 25, 2018. Finding are 1. Based upon review of D-Dimer calibration verification documentation records, the last documented calibration verification performed was October 25, 2017. 2. Note attached to front of instrument reminding calibration verification due April 25, 2018. 10 patients tested since calibration verification due. 3. Verified calibration verification not performed by interview with technical consultant #1 at 11:10 on June 21, 2018. Therefore the accuracy and the reliability of the testing can not be verified.