

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0660750	(X3) Date Survey Completed 12/05/2018
Name of Provider or Supplier Stonewall Memorial Hospital	Street Address, City, State 821 N Broadway, Aspermont, TX	
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
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) -- (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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's calibration verification records for 2017 and 2018, and staff interview, the laboratory failed to perform calibration verification of the analytes Amylase and Ammonia, tested on the Vitros 350 chemistry analyzer at least once every six months. The findings included: 1. Review of calibration verification (linearity) procedures found documentation of calibration verification activities for Amylase and Ammonia as follows: Ammonia - last calibrated on March 29, 2018</p>

using Lot/Gen 2916-7667 previously calibrated August 31, 2017 using Lot/Gen 1-17-4591 Amylase - last calibrated May 26, 2018 using Lot/Gen 6046-8224 previously calibrated January 26, 2018 using Lot/Gen 6042-2554 2. Interview of the Laboratory Director conducted December 5, 2018 at 12:15 PM confirmed that no additional records for calibration verification were available for review. She stated that she does calibration verifications when she finds that calibration procedures exceed 6 months, but she did not have supplies so she did not get it done.

D5807

TEST REPORT
CFR(s): 493.1291(d)

Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:
Based on a review of the laboratory's hematology reference range establishment study, Sysmex XS-1000i operator's manual operator's manual, laboratory policy, and interview with the laboratory director, the laboratory failed to use pertinent reference intervals (patient normal values) on the patient final reports for 10 of 10 final patient reports review on December 5, 2018. The findings included: 1. Based on the Sysmex validation instructions and related normal patient reference range establishment study, the laboratory performed a statistical analysis of normal patient specimens to establish a normal patient reference range for complete blood count parameters in July of 2014. Example of established normal ranges from the laboratory's study: Parameter: White blood cell count (WBC) Female normal range: 4.41 - 10.89 Parameter: Hemoglobin Male normal range: 12.47 - 17.55 Parameter: Platelet count Female normal range: 165.45 - 344.21 2. Based on review of the laboratory's procedure "COMPLETE BLOOD COUNT", effective 3.1.2014, revised 10/29/2015, and 9/24/2018, the procedure states the following on pages 17 and 18: "XIII. NORMAL RANGE Parameter: White blood cell count (WBC) Female normal range: 4.6 - 11.0 Parameter: Hemoglobin Male normal range: 13.0 - 18.0 Parameter: Platelet count Female normal range: 150 - 450 The source of the normal patient ranges in not listed in the pertinent literature section of the procedure. 3. Based on a review of the manufacturer's reference ranges provided in operator's manual (Code 461-2629-2), on page 1-6, the manufacturer provided reference ranges differ from those in the laboratory's procedure. 4. Based on a review of 10 random final patient reports for complete blood counts, the reference ranges on the final patient report correlate with the reference ranges from the laboratory's procedure but do not correlate with the laboratory's established normal patient range or the manufacturer's suggested range. 5. In an interview at 12:12 on 12/05/2018 in the laboratory, the Laboratory Director stated she thought the ranges currently printed on patient reports and listed in the laboratory's procedure may have originated on a different platform the laboratory had prior to the Sysmex XS-1000i.