Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0508135	12/04/2018
Name of Provider or Supplier	**Street Address, City, State**	
Hamlin Memorial Hospital	632 Nw 2nd Street, Hamlin, 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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, the Sysmex hematology analyzer operator's manual, random review of patient records, and interview with the Laboratory Director, the laboratory failed to define reference intervals (normal values) in the procedure manual for complete blood counts (CBC). The findings included: 1. Based on review of the laboratory's procedure "COMPLETE BLOOD COUNT OF WHOLE BLOOD ON THE SYSMEX KX-21N", approved for use by the previous Laboratory Director on November 15, 2005, on page 18 of 21, the procedure states the following: "X. REPORTING RESULTS A. KX-21N ADULT REFERENCE RANGE

	Complete this section with your laboratory's normal reference range." This portion of the document has a table with complete blood count analytes and the reference ranges are not listed. Below the adult reference range table, the procedure lists the following: "B.KX-21N PEDIATRIC REFERENCE RANGE: Complete this section with your laboratory's pediatric reference range." This portion of the document has a table with complete blood count analytes and the reference ranges are not listed. 2. Based on a review of the Sysmex KX-21N operator's manual (Code No. 461-2264-1), on page 2-30, the operator's manual states the following: "7. EXPECTED RESULTS Reference intervals (normal population reference ranges) were developed for the KX-21N using normal individuals. The ranges for each parameter ---WBC, RBC, Hemoglobin, Hematocrit, MCV, MCH, MCHC, RDW-CV, RDW-SD, Platelet, MPV, Lym percent and number, were determined and displayed in Table 1-16-1." Table 1-16-1 is displayed below the text. Based on a random review of reference ranges from Table 1-16-1: Analyte: White Blood Cell count (WBC) Range for Males - 2.6 - 8.8 Analyte: Hemoglobin Range for females - 9.9 - 13.6 Analyte: Percent Neutrophils Range for males: 33 - 69 percent 3. Based on a random sampling of male and female patients, the laboratory final patient report included reference ranges that were not listed on the policy, the operator's manual, or verified upon installation of the Sysmex XS-21N. From a random sampling of final patient reports: Analyte: White Blood Cell count (WBC) Range for Males - 4.0 - 11.0 Analyte: Hemoglobin Range for females - 11.5 - 16.5 Analyte: Percent Neutrophils Range for males: 45 - 70 percent 4. In an interview at 14:32 hours on 12/04/2018 in the laboratory, the Laboratory Director stated that he did not know the source or origin of the reference ranges that were currently printed on patient final reports. The Laboratory Director stated that the laboratory had previously received feedback from Emergency Room physicians regarding the lack of pediatric reference ranges.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of the Tosoh chemistry analyzer verification study, thyroid stimulating hormone (TSH) assay instructions for use, random review of patient reports, and interview with the Laboratory Director, the laboratory failed to verify the normal patient reference range for TSH prior to reporting test results. The findings included: 1. Based on review of the Tosoh chemistry analyzer method verification instructions "Method Validation" (October 2010), the instructions state the following: "Each laboratory that introduces an unmodified, FDA cleared or approved test system must do the following before reporting patient test results: 1) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: a. Accuracy b. Precision c. Reportable Range of test results for the test system. 2) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. The four performance tests listed above are required for CLIA

	compliance. Each laboratory should establish protocols and procedures in accordance with performance criteria appropriate for the patient population being tested and interpretation of regulations under which the laboratory operates." 2. Based on review of the TSH assay instructions for use, under the heading "EXPECTED VALUES", the document states the following: "Each laboratory should determine a reference interval which corresponds to the characteristics of the population being tested. As with all diagnostic procedures, clinical results must be interpreted with regard to concomitant mediations administered to the patient (12). Reference Ranges: The intervals given here were determined in serum samples from 497 apparently health Asian individuals and 166 apparently healthy Caucasian individuals, respectively. Asian Number of Samples (n): 497 Reference Interval: 0.38 - 4.31 mIU/L Caucasian Number of Samples (n): 166 Reference Interval: 0.40 - 3.60 mIU/L" 3. Based on a review of the verification study for the Tosoh chemistry analyzer, the laboratory had verified the following characteristics prior to reporting patient test results: accuracy, precision, reportable range. These were approved by the laboratory director on 3/22/2017, 3/9 /2017, and 3/9/2017 respectively. 4. Based on a random sampling review of 10 final patient test results, the reference range in use for all patients (Asian and Caucasian and all others) was listed as 0.38 - 4.31. 5. In an interview at 14:35 hours on 12/04 /2018 in the laboratory, the Laboratory Director stated that he had begun the process of collecting normal samples to verify the reference range for TSH, but the normal patient range had not been verified prior to performing patient testing. Key: TSH stands for thyroid stimulating hormone
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) 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. This STANDARD is not met as evidenced by: Based on a review of calibration verification records, calibration records, verification study records, and interview with the Laboratory Director, the laboratory failed to perform calibration verification procedures at least once every 6 months for the Prostate-specific antigen (PSA) analyte for 18 of 18 months between April 2017 and December 4, 2018. The findings included: 1. Based on review of calibration

	verification records, the laboratory had not performed calibration verification procedures for PSA between the initial installment in March/April 2017 and the date of the survey, December 4, 2018 (18 months). 2. Based on review of the calibration records for the PSA assay, the assay was calibrated with 2 points. Laboratories must perform and document calibration procedures following the manufacturer's test system instructions, using calibration materials provided or specified, and at a frequency that meets or exceeds that recommended by the manufacturer. Where the manufacturer does not provide such instruction, the laboratory may calibrate using 3 or more levels of calibration materials that include a low, mid, and high value at least every 6 months. 3. In an interview at 14:37 hours on 12/04/2018 in the laboratory, the Laboratory Director stated that he had not tracked the calibration verification for the PSA and failed to perform calibration verification procedures at least every six (6) months between the initial installment of the Tosoh chemistry analyzer and the survey date (12.04.2018).