Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0660706	02/20/2019
Name of Provider or Supplier	**Street Address, City, State**	
Hardeman County Memorial Hospital	402 Mercer St, Quanah, 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
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on surveyor observations and interview with facility personnel, the laboratory failed to ensure 6 of 6 royal blue top blood collection tubes and 2 of 3 grey top Sodium Fluoride tubes were available for use in collecting patient specimens on February 20, 2019. The findings included: 1. Based on surveyor observations on Wednesday, February 20, 2019 in the phlebotomy room, the surveyor observed the following blood collection tubes in the rack beside the phlebotomy chair available for collecting patient specimens: 6 of 6 royal blue blood collection tubes Manufacturer: Becton Dickinson Lot: 8011601 Expiration: 2019-01-31 Elapsed time: the tubes were expired by 20 days 2 of 3 grey top Sodium Fluoride blood collection tubes Manufacturer: Becton Dickinson Lot: 7180569 Expiration: 12-31-2018 Elapsed time: the tubes were expired by 51 days 2. In an interview at 16:51 hours on 2/20/2019 in the phlebotomy room, the Laboratory Manager confirmed the blood collection tubes were available for use beyond the expiration date printed on the tubes.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

	This STANDARD is not met as evidenced by: Based on review of the MTS diluent dispenser instructions for use, laboratory maintenance records, and interview with facility personnel, the laboratory failed to perform required weekly maintenance procedures for 1 of 1 repetitive dispenser for 38 of 52 weekly cleaning events in 2018. The findings included: 1. Based on review of the Ortho MTS Dispenser Repetitive Dispenser of 0.5 or 1.0 mL Instructions for Use (Pub. No. J33098_EN), on page 3 of 5, the document states the following: "Cleaning: The dispenser should be cleaned on a weekly basis as follows: 1. Remove the dispenser from the diluent bottle. Dispense diluent until the outlet line is empty. 2. Rise and decant the inside of the cap with 70 percent Isopropyl Alcohol. 3. Rinse and decant the inside of the cap with copious amounts of deionized or distilled water. 4. Aspirate with 70 percent Isopropyl Alcohol a minimum of 15 times through the dispenser into a waste receptacle. 5. Remove the dispenser from the 70 percent Isopropyl Alcohol solution. 6. Dispense into the waste receptacle the remained 70 percent Isopropyl Alcohol that is left in the tubing until the outlet line is empty. 7. Wipe the inlet tubing with a soft cloth so as not to contaminate the deionized or distilled water with the 70 percent Isopropyl Alcohol solution. 8. Flush the dispenser with freshly drawn deionized or distilled water a minimum of 20 dispenses into a waste receptacle. 9. Remove the dispenser from the deionized or distilled water. 10. Dispense into a waste receptacle the remained water that is left in the tubing until the outlet line is empty. 11. Wipe dry the inlet tubing wand outer dispenser surface with a soft, clean cloth. 12. If ready for use, prime line a minimum of one time, with appropriate diluent to be dispensed. If the dispenser will not be used for a while, store dry." This document was laminated and stored in the blood bank area of the laboratory. 2. Based on review of laboratory maintenance records "Quality Control Record", MTS Dispenser Weekly Cleaning was documented as being performed on the following 14 dates in 2018: 1/4/2018 1/11/2018 2/5/2018 2/28/2018 3/8/2018 4/9 /2018 5/17/2018 6/26/2018 7/16/2018 8/23/2018 9/6/2018 10/19/2018 11/21/2018 12 /28/2018 There are 52 weeks per calendar year. The laboratory documented the weekly maintenance 14 times. Weekly maintenance was not performed for 38 of 52 weeks. The laboratory reported an annual volume of 259 tests annually for immunohematology on the CMS-116 collected the day of the survey. 3. In an interview at 15:06 hours on 2/20/2019 in the laboratory, when asked to describe how weekly maintenance was performed on the MTS diluent dispensers, the Laboratory Manager stated the frequency had been changed from weekly to monthly before she had assumed the responsibilities as Laboratory Manager in October of 2018 and that it was the Lab Manager's understanding there was a product notification or similar document that initiated the change in maintenance frequency.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on review of hematology control instructions for use, surveyor observations, quality control record review, and interview with facility personnel, the laboratory failed to follow manufacturer instructions for setting acceptability criteria for 2 of 2 lots of control materials currently in use to detect immediate error in hematology analyzer performance. The findings included: 1. Based on review of the Sysmex E CHECK (XS) control instructions for use, under Performance characteristics and limitations, the document states the following: "The mean assay values for each parameter of e-CHECKS(XS) are derived from replicate analysis on whole blood calibrated instrumentation. The mean values obtained on e-CHECKS(XS) should be within the expected ranges. The expected ranges listed on the assay sheet represent estimates of inter-laboratory variation for each parameter. These expected ranges should not be used as QC file limits." And; "e-CHECKS(XS) is intended for use only on Sysmex XS-Series analyzers with Sysmex reagents. E-CHECKS(XS) assay targets and limits are model specific. 2. Based on review of the Sysmex Product Notification "Sysmex Evidence Based Control Limits" (07/2017), under Action, states the following: "1. Enter model specific control limits from the table attached. 2. Auto-set the control target value and limit for each parameter using minimum of 10 analyses. 3. Verify target values are within published assay ranges. 4. Analyze QC according to your laboratory's established protocols." 3. Based on surveyor observations at 16:42 hours on 2/20/2019, the Limit Range percent for each analyte was set at 100 percent control lots 83520805 and 83520806. For example, Control Level 3, Lot 83520806, the analyte mean platelet volume (MPV) had a target of 9.9 and the Limit Range percent was set at 100 percent. According to the "Sysmex Evidence Based Control Limits" (07/2017), the Limit Range Percent should have been 6.3 percent. Another example: Control Level 2, Lot 83520805, the analyte Hemoglobin was had a target of 11.6 and a Limit Range percent of 100 percent. According to the "Sysmex Evidence Based Control Limits" (07/2017), the Limit Range Percent should have been 4.3 percent. The ranges of control acceptability were too wide for the laboratory to detect immediate error. 4. In an interview at 16:45 hours on 2/20/2019, the Laboratory Manager stated the laboratory had been unaware of the product notification "Sysmex Evidence Based Control Limits" (07/2017) and had not known how to set acceptability criteria on the Sysmex XS-1000i hematology analyzer.
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 a review of laboratory policy, quality control records, quality control peer review records, and interview with laboratory personnel, the laboratory failed to establish a step by step procedure for establishing quality control acceptability criteria for 1 of 1 lot of control material reviewed on February 20, 2019. The findings included: 1. Based on review of the procedure "Laboratory Policies", last reviewed by the laboratory director on 10/22/2018, the procedure states the following on page 12: "8. The mean and standard deviation will be established "in-house" with results being compared to other laboratories using the same instrument and reagent. At least ten comparisons will be run on each new lot of controls." 2. Based on review of the Bio-Rad Immunoassay Plus instructions for use, under Assignment of Values, states the following: "It The mean values and corresponding plus/minus 3SD ranges in the Assignment of Values Data Charts were derived from replicate analysis and are specific for this lot of product. Data from Unity Interlaboratory Program are included in the determination of some ranges. The tests listed were performed by the manufacturer and/or independent laboratories using manufacturer supported reagents and a representative sampling of this lot of product. It is recommended that each laboratory establish its own acceptable ranges and use those provided only as guides. Laboratory established ranges may vary from those listed during the life of this control. Variations over time and between laboratories may be caused by differences in laboratory technique, instrumentation and reagents, or by manufacture test method modifications." 3. Based on review of quality control records, the laboratory was using a target mean of 0.8 and a target one standard deviation of 0.07 for Level 1 Free T4, Lot: 40961. The plus/minus two (2) standard deviation range was 0.66 - 0.94. This information differed from other sources. The ranges provided from Bio-Rad, to be used only as guides were as follows: Target: 0.829 1 SD: 0.053 The cumulative statistics for the laboratory: Cumulative mean: 0.788 Cumulative 1 SD: 0.044 With a sample size of 255 points, contributed by this laboratory on this analyzer. The cumulative statistics from a peer group of other laboratories using an Access II chemistry analyzer and this method of Free T4: Peer cumulative mean: 0.781 Peer cumulative 1 SD: 0.046 With a sample size of 38,939 points, contributed by this laboratory and other laboratories using the Free T4 reagent on an Access II chemistry analyzer. The 1SD target used by the laboratory was 27.6 percent larger than the 1 SD target provided as guide by the Bio-Rad instructions for use, 39 percent greater than the peer cumulative 1 SD, 45.6 percent larger than the lot-to-date cumulative statistics generated by the laboratory. 4. In an interview with the laboratory manager at 15:45 hours on 2/202/2019 in the laboratory, when asked to describe the laboratory policy for establishing acceptability criteria, the Laboratory Manager stated the laboratory used the peer review data to guide QC limit decisions, but did not have an evidence based policy on how to establish QC limits.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by:

	Based on review of laboratory policy, quality control records, corrective action records, patient records, and interview with facility personnel, the laboratory failed to document all corrective actions taken on 1/5/2019 and 1/11/2019 and the laboratory failed to evaluate 2 of 2 patients tested in the unacceptable run and since the last acceptable control for corrective actions on 11/18/2018. The findings included: 1. Based on review of the procedure "Laboratory Policies", last reviewed by the laboratory director on 10/22/2018, the procedure states the following on page 12: "When the run is rejected because the method is out-of-control: a. Determine the type of error occurring. A random error will be indicated by 1-3S and R4S rule. A Systematic error will be indicated by 2-2S, 4-1S, and by 1-3S when the error is large. b. Refer to trouble shooting guides and inspect the analytical method. c. Correct the problem, then analyze the patient and control samples again, and test for statistical control as before. Do not include the control data from the previously rejected run. d. Consult a supervisor for any decision to report data when there is a lack of statistical control." 2. Based on a review of quality control records in the laboratory information system (LIS) and the quality control software package on the Beckman chemistry analyzer, the laboratory failed to document corrective actions for the following unacceptable control values: Creatinine, Level 1 (Lot 45791) Acceptable levels: 0.57 - 0.77 1/5/2019 at 18:07 hours, value is unacceptable at 0.79 1/5/2019 at 18:26 hours, value is unacceptable at 0.86 1/5/2019 at 18:42 hours, value is 2SD above the mean at 0.77 1/5/2019 at 19:02 hours, value is unacceptable at 0.90 1/5/2019 at 19:12 hours, value is within acceptable ranges at 0.62 In review of the quality control records from the LIS, only two controls values are displayed: 1/5/2019 at 18:37 hours, value is 0.77 1/5/2019 at 19:07 hours, value is 0.62 No corrective actions are documented for any of the repeated quality control values outside acceptable limits. No documentation was available for review of assessing patients' specimens tested since the last acceptable quality control run on 1/4/2019. Creatinine, Level 1 (Lot 45791) Acceptable levels: 0.57 - 0.77 1/11/2019 at 20:06 hours, value is unacceptable at 0.80 1/11/2019 at 20:20 hours, value is unacceptable at 0.81 1/11/2019 at 20:31 hours, value is within limits at 0.63 The values of 0.8 and 0.81 do not appear on the LIS quality control record. No corrective actions are documented for any of the repeated quality control values outside acceptable limits. No documentation was available for review of assessing patients' specimens tested since the last acceptable quality control run on 1/11/2019 at 07:22 hours. Creatinine, Level 3 (Lot 45793) Acceptable levels: 5.72 - 6.48 11/18/2018 at 07:34 hours, value is outside acceptable limits at 5.62 11/18 /2018 at 08:20 hours, value is acceptable at 6.04 On the LIS quality control record, only the 6.04 value is recorded for 11/18/2018. On the laboratory document "Calibration Log", Creatinine was re-calibrated on 11/18/2018. Under the "Reason for Calibrating", "failed QC" is notated. There is no documentation of assessing patients tested since the last acceptable quality control on 11/17/2018. Based on review of patient records, two patient specimens were run between the last acceptable quality control on 11/17/2018 at the recalibration on 11/18/2018: Patient: 88440 Creatinine: 0.59 Patient: 88464 Creatinine: 0.94 3. In an interview at 13:45 hours on 2/20/2019 in the laboratory, the Laboratory Manager stated the laboratory had not established a policy to evaluate patients tested since the last acceptable quality control as a part of documenting corrective actions. The lab manager stated that she had been unaware of the repeats and lack of corrective action documentation because she had relied on the quality control program on the LIS.
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 the laboratory's policies and procedures, Bio-Rad and Sysmex control instructions for use, quality control records, surveyor observation, and staff interview, the laboratory failed to establish and follow written policies and procedures to monitor, assess and correct problems in the analytic laboratory systems specified at 493.1251 through 493.1283. The findings included: 1. The laboratory's quality assurance activities failed to detect that the laboratory failed to ensure 6 of 6 royal blue top blood collection tubes and 2 of 3 grey top Sodium Fluoride tubes were available for use in collecting patient specimens on February 20, 2019. Refer to D5417. 2. The laboratory's quality assurance activities failed to detect that the laboratory failed to perform required weekly maintenance procedures for 1 of 1 repetitive dispenser for 38 of 52 weekly cleaning events in 2018. Refer to D5429. 3. The laboratory's quality assurance activities failed to detect that the laboratory failed to follow manufacturer instructions for setting acceptability criteria for 2 of 2 lots of control materials currently in use to detect immediate error in hematology analyzer performance. Refer to D5441. 4. The laboratory's quality assurance activities failed to detect that the laboratory failed to establish a step by step procedure for establishing quality control acceptability criteria for 1 of 1 lot of control material reviewed on February 20, 2019. Refer to D5469. 5. The laboratory's quality assurance activities failed to detect that the laboratory failed to document all corrective actions taken on 1 /5/2019 and 1/11/2019 and the laboratory failed to evaluate 2 of 2 patients tested in the unacceptable run and since the last acceptable control for corrective actions on 11 /18/2018. Refer to D5783. 6. Quality Assessment (QA) is an ongoing review process that encompasses all facets of the laboratory's technical and non-technical functions at all location/sites where testing is performed. QA also extends to the laboratory's interactions with and responsibilities to patients, physicians, and other laboratories ordering tests, and the non-laboratory areas or the facility of which it is a part. When the laboratory discovers an error or identifies a potential problem, actions must be taken to correct the situation. This correction process involves identification and resolution of the problem, and development of policies that will prevent recurrence. Policies for preventing problems that have been identified must be written as well as communicated to the laboratory personnel and other staff, clients, etc., as appropriate. Over time, the laboratory must monitor the corrective action(s) to ensure the action(s) taken have prevented recurrence of the original problem. All pertinent laboratory staff must be involved in the assessment process through discussions or active participation. QA of the Analytic System includes assessing: o Test procedures; o Accurate and reliable test systems, equipment, instruments, reagents, materials, and supplies; o Specimen and reagent storage condition; o Equipment/instrument/test /system maintenance and function checks; o Establishment and verification of method performance specifications; o Calibration and calibration verification; o Control procedures; o Comparison of test results; o Corrective actions; and o Test records. In an interview at 17:00 hours on 2/20/2019 in the laboratory, the Laboratory Manager stated the laboratory did not have quality assessment procedures in place that would have identified the deficiencies listed above.
D6022	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)

	The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, Bio-Rad and Sysmex control instructions for use, quality control records, surveyor observation, and staff interview, the laboratory director failed to ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur in 2018. The findings included: 1. The laboratory director failed to ensure that the laboratory followed manufacturer instructions for setting acceptability criteria for 2 of 2 lots of control materials currently in use to detect immediate error in hematology analyzer performance. Refer to D5441. 2. The laboratory director failed to ensure that the laboratory established a step by step procedure for establishing quality control acceptability criteria for 1 of 1 lot of control material reviewed on February 20, 2019. Refer to D5469. 5. The laboratory director failed to ensure that the laboratory established a policy to document all corrective actions taken for unacceptable quality control values and establish a policy to evaluate patients tested in the unacceptable run and since the last acceptable control when corrective actions involve manipulating analytic components just as re-calibration, replacing a reagent, or performing maintenance. 6. The laboratory director failed to ensure that the laboratory established a Quality Assessment (QA) policy an ongoing review process that encompasses all facets of the laboratory's technical and non-technical functions at all location/sites where testing is performed. QA also extends to the laboratory's interactions with and responsibilities to patients, physicians, and other laboratories ordering tests, and the non-laboratory areas or the facility of which it is a part. When the laboratory discovers an error or identifies a potential problem, actions must be taken to correct the situation. This correction process involves identification and resolution of the problem, and development of policies that will prevent recurrence. Policies for preventing problems that have been identified must be written as well as communicated to the laboratory personnel and other staff, clients, etc., as appropriate. Over time, the laboratory must monitor the corrective action(s) to ensure the action(s) taken have prevented recurrence of the original problem. All pertinent laboratory staff must be involved in the assessment process through discussions or active participation. QA of the Analytic System includes assessing: o Test procedures; o Accurate and reliable test systems, equipment, instruments, reagents, materials, and supplies; o Specimen and reagent storage condition; o Equipment/instrument/test /system maintenance and function checks; o Establishment and verification of method performance specifications; o Calibration and calibration verification; o Control procedures; o Comparison of test results; o Corrective actions; and o Test records. In an interview at 17:00 hours on 2/20/2019 in the laboratory, the Laboratory Manager stated the laboratory did not have quality assessment procedures in place that would have identified the deficiencies listed above. Refer to D5793.