Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0659838	09/23/2020
Name of Provider or Supplier	**Street Address, City, State**	
Throckmorton County Memorial Hospital	802 North Minter Avenue Box 729, Throckmorton, 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
D2094	ROUTINE CHEMISTRY CFR(s): 493.841(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing records, corrective actions, and interview with facility personnel, the laboratory failed to take remedial action for unsatisfactory Albumin scores from the third event of 2019. The findings included: 1. Based on review of the American Proficiency Institute (API) testing scores, the laboratory received the following scores: 3nd event 2019 Albumin - 0 percent Scores less than 80 percent constitute unsatisfactory analyte performance. 2. Laboratory submitted results and acceptable ranges are as follows: Albumin Lab value Acceptable range 1.5 1.7 - 2.1 1.7 1.9-2.4 2.2 2.5-3.2 2.5 2.8-3.5 2.8 3.2-4.1 3. The laboratory's corrective action documentation included the following comments: "Albumin failed on all 5 samples. Tech did not notice QC was out that day. Albumin recalibrated 9/14. Proficiency samples rerun 10/3/2019; acceptable. 4. In an interview at the exit conference on 09/23/2020 at 11:58 hours, the laboratory director confirmed that the she remembers addressing patients that may have been affected but could not find any documentation of the remedial actions.
D2105	ENDOCRINOLOGY CFR(s): 493.843(e)

	(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing records, corrective actions, and interview with facility personnel, the laboratory failed to take remedial action for unsatisfactory Free Thyroxine scores from the first event of 2019. The findings included: 1. Based on review of the American Proficiency Institute (API) testing scores, the laboratory received the following scores: 1st event 2019 Free Thyroxine - 40 percent Scores less than 80 percent constitute unsatisfactory analyte performance. 2. Laboratory submitted results and acceptable ranges are as follows: Free Thyroxine Lab value Acceptable range 2.4 1.4-2.2 4.5 3.2-4.3 5.5 4.1-5.5 0.7 0.3-0.8 4.0 2.6-3.8 3. The laboratory's corrective action documentation included the following comments: "Calibration error; recalibration with rerunning of samples, samples now within limits." There is was no documentation of assessing patient results that may have been run on the unacceptable calibration. 4. In an interview at the exit conference on 09/23 /2020 at 11:58 hours, the laboratory director confirmed that the she remembers addressing patients that may have been affected but could not find any documentation of the remedial actions.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of the Vitros chemistry analyzer operator's manual, calibration and quality control records, and interview with facility personnel, the laboratory failed to follow manufacturer instructions to perform quality control checks after analyte calibrations. The findings included: 1. Based on review of the Vitros chemistry analyzer operator's manual, quality control checks should be performed following a calibration. On page 11-1, the manual states the following: "In addition, it is important to check quality control fluids in the following situations: *following a calibration *when you load a cartridge with a new slide lot number *when service, other than routine maintenance, has been performed on the analyzer (for example, lamp replacement) *following entry of a new white-reference correction factor for a reflectometer filter. *when there are changes in the laboratory's ambient room temperature greater than plus/minus 5 degrees Celsius from the temperature at the time of test calibration *when the analyzer has experienced unintentional power loss." On page 6-28, the manual states the following: "Verify each calibration by analyzing quality control material that has values assigned for the analyzer and analyte. You should analyze at least two levels of controls; a normal and an abnormal level. Run

	quality control samples in duplicate. The calibration is verified if: *The quality control results are within the acceptable ranges established by your laboratory * The analyzer didn't report any calibration errors." 2. Based on review of calibration records, Albumin was calibrated at 16:56 hours on 9/13/2019, after the last QC repeat at 16:20 hours on 9/13/2019. QC was not performed again until 10:52 hours on 9/14 /2019. Based on review of calibration records, Albumin was calibrated on 9/14/2019 at 11:18 hours. Quality control was not performed until 09:38 hours on 9/15/2019. Elapsed time: 22 hours, 20 minutes. 3. In an interview conducted at 11:58 hours on 9 /23/2019in the office, the laboratory manager stated they had discovered that some testing personnel had failed to perform quality control after performing an analyte calibration and had spoken to testing personnel involved.
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 manufacturer's instructions, maintenance logs, and interview, the laboratory failed to perform maintenance as defined by the manufacturer for 2 of 13 months on the CELL-DYN Emerald, and 4 out of 20 weeks for the OPTI-CCA-TS. Findings follow. I. Review of the Cell-Dyn Emerald Operator's Manual, Rev 9140853F- August 2012, under Section 9 Service and Maintenance stated, "The maintenance schedule outlined in this section minimizes operational problems with the CELL-DYN Emerald. The recommended intervals are based on instruments operating in laboratories analyzing up to 50 specimens per day from a general patient population." Under Monthly Maintenance for Bleach Cleaning stated, "Cleaning the system with a bleach solution is performed monthly or as needed when a measurand is repeatedly rejected." Review of the Emerald Maintenance Log from September 2019 to September 2020 showed the monthly maintenance was not performed in July 2020. Review of the Log Report printed from the Emerald showed documentation of maintenance performed on the Emerald from 6/22/2020 - 9/23/2020. For the BLH (Bleach) column, it showed maintenance was performed on 08/28/2020 and 09/23 /2020. There was no maintenance performed in June or July 2020. Interview with testing personnel (TP) #1 on the CMS form 209 at 1330 in the lab on 9/22/2020 verified there was no monthly maintenance performed in July 2020. And interview with TP #1 on the CMS form 209 at 0915 in the office on 9/23/2020 after a review of the Maintenance Log, performance of the bleach monthly maintenance, and review of the Log Report showing its performance, verified there was no documentation of the monthly maintenance performed in June 2020 on the Log Report. II. Review of the OPTI-CCA-TS Operator's Manual, Rev PD7040 H, under Weekly Maintenance stated, "Once a week, the Sample Measurement Chamber (SMC) must be cleaned. Open the top cover and clean the optics surface as well as the underside of the SMC cover with a lint-free cloth, dampened with a dilute alcohol or ammonia-based cleaner as needed. Be sure to remove all blood residue." Review of the Blood Gas Maintenance Log from May 2020 to September 2020 showed the frequency required was monthly, and was being performed once per month on May 27, June 8, July 14. and August 28. Interview with TP#1 on the CMS form 209 at 1628 in the office on 9 /22/2020 acknowledged the only maintenance she knows about is changing the pump and was not aware of weekly maintenance.

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 the laboratory's IQCP (Individualized Quality Control Plan), manufacturer's quality control (QC) ranges, QC records, and interview, the laboratory failed to define what to do if external QC fails for D-Dimer on the Alere Triage. Findings follow. Review of the laboratory's IQCP titled Quality Control Plan for Alere Triage MeterPro DDimer contains no information on the steps to take if external QC fails. Review of the Triage Total 5 Level 1 Control, Lot C3452AN, QC range for D-Dimer was 265 - 551 ng/mL. Review of the D-Dimer QC Lot Review from 12/27/18 - 12/23/19 showed for Lot 3452 tested on 4/27/2019, 5/27/2019. 6/27 /2019, and 7/27/2019 Level 1 was out of range on 7/27/2019 with a value of 567 ng /mL (Level 2 was within range), and QC was not performed successfully again until 8 /24/2019. Interview with the laboratory director at 1500 in the office on 9/23/2020 confirmed the IQCP does not address external QC failure and what to do if there is a failure.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's IQCP (Individualized Quality Control Plan), manufacturer's quality control (QC) ranges, QC records, patient testing summary report, and interview, the laboratory failed to ensure the controls met the manufacturer's criteria for acceptability before reporting patient test results for D-Dimer on the Alere Triage for 1 of 13 months reviewed. Findings follow. Review of the laboratory's IQCP titled Quality Control Plan for Alere Triage MeterPro DDimer stated, "Based on the risk assessment and Quality Assessment, the quality control plan consists of the following instructions that are provided in explicit detail in Quality Control and Acceptability of result of Ddimer assay and are summarized below: 1. External liquid QC (1 known normal and 1 known abnormal) performed per lot /shipment before or concurrently with placing the reagents into use for patient testing... 4. External liquid QC (1 known normal and 1 known abnormal) performed at least every 30 days." Review of the Triage Total 5 Level 1 Control, Lot C3452AN, QC range for D-Dimer was 265 - 551 ng/mL. Review of the D-Dimer QC Lot Review

	from 12/27/18 - 12/23/19 showed for Lot 3452 tested on 4/27/2019, 5/27/2019. 6/27 /2019, and 7/27/2019 Level 1 was out of range on 7/27/2019 with a value of 567 ng /mL (Level 2 was within range), and QC was not performed successfully again until 8 /24/2019. Review of the patient testing summary report for D-Dimer showed 6 patients were reported from 7/27/2019 - 8/23/2019, patient # and date of testing: 10013825 (7/30/2019), 10013836 (7/31/2019), 10013843 (8/1/2019), 10013928 (8/12 /2019), 10013942 (8/13/2019), 10013943 (8/13/2019). Interview with testing personnel (TP) #1 on the CMS form 209 at 1325 in the office on 9/23/2020 verified she thought the print outs told her when QC was out of range.
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 the laboratory's quality control records, corrective action records, and interview with facility personnel, the laboratory failed to evaluate all patients tested since the last acceptable quality control values when the results of control materials failed to meet the laboratory's established limits. The findings included: 1. Review of quality control records for the Vitros chemistry analyzer indicated the following quality control materials were repeated between 09/10/2020 and 09/15/2020 for Albumin. QC1 - Albumin 09/10/2019 -- 2.43 - acceptable 9/11/2019 1.94 - Flag F3 9/12/2019 at 15:05 - 1.83Flag F3 9/12/2019 at 15:31 - 1.83 - Flag F3 9/13/2019 at 12:56 - Flag F3 9/13/20219 at 16:20 Flag F3 9/14/20219 at 10:52 Flag F2 9/15/20219 - QC is within limits. There was no documentation of the corrective actions taken for the quality control values repeated above other than "ALB calibrated" on 9/13/2019. Based on review of calibration records, Albumin was calibrated at 16:56 hours on 9/13 /2019, after the last QC repeat at 16:20 hours on 9/13/2019. Based on review of patient records, 18 patient samples were tested for Albumin between 9/10/2019 and 9 /15/2019. 2. Based on a review of Blood Urea Nitrogen (BUN) quality control records from June 24th, 2020: QC 2 BUN 6/23/2020 - QC is within limits 6/24/2020 at 08:15 - 45.8 - Flag F3 6/24/2020 at 08: 30 - 47.9 - Flag F3 6/24/2020 at 09:30 - 42.6 - Flag F3 BUN is calibrated at 12:07 hours on 6/24/2020 QC 2 is within limits at 12:22 on 6 /24/2020. Corrective actions were documented. There was no evaluation of patients tested since the last acceptable quality control. 3. In an interview at 14:37 hours on 09 /23/2020 in the conference room, Testing Person 1 confirmed there was no documented corrective action for the control actions taken as listed above. This is a repeat finding from the last recertification inspection.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems

	quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of maintenance records, calibration records, quality control records, patient testing records, and interview with facility personnel, the laboratory quality assessment activities failed to identify and correct issues in analytic systems. The findings included: 1. The quality assessment activities failed to identify and correct that the laboratory failed to follow manufacturer instructions for verifying calibrations. Refer to D5411. 2. The quality assessment activities failed to identify and correct that the laboratory failed to perform maintenance as required by the manufacturer for the Abbott Emerald hematology analyzer and the OPTI CCA blood gas analyzer. Refer to D5429. 3. The quality assessment activities failed to identify and correct that the laboratory failed to define what to do if external QC fails for D-Dimer on the Alere Triage. Refer to D5441. 4. The quality assessment activities failed to identify and correct that the laboratory failed to ensure the controls met the manufacturer's criteria for acceptability before reporting patient test results for D-Dimer on the Alere Triage for 1 of 13 months reviewed. Refer to D5481. 5. The quality assessment activities failed to identify and correct that the laboratory failed to evaluate all patients tested since the last acceptable quality control run when quality control materials failed to meet established limits. Refer to D5783.
D6020	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 program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of quality control records, patient records, and interview with the laboratory director, the laboratory director failed to ensure the quality control program was maintained to assure the quality of laboratory services. The findings included: Based on review of the laboratory's IQCP (Individualized Quality Control Plan), manufacturer's quality control (QC) ranges, QC records, and interview, the laboratory failed to define what to do if external QC fails for D-Dimer on the Alere Triage. Refer to D5441. Based on review of the laboratory's IQCP (Individualized Quality Control Plan), manufacturer's quality control (QC) ranges, QC records, patient testing summary report, and interview, the laboratory failed to ensure the controls met the manufacturer's criteria for acceptability before reporting patient test results for D-Dimer on the Alere Triage for 1 of 13 months reviewed. Refer to D5481. Based on review of the laboratory's quality control records, corrective action records, and interview with facility personnel, the laboratory failed to evaluate all patients tested since the last acceptable quality control values when the results of control materials failed to meet the laboratory's established limits. Refer to D5783.