Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0489109	05/09/2018
Name of Provider or Supplier	**Street Address, City, State**	
West Texas Medical Associates / Lab	3605 Executive Drive Suite 117, San Angelo, 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
D0000	A routine recertification inspection was performed on May 8th, 2018 and May 9th, 2018. The laboratory is in compliance with all Conditions of Participation found in the CLIA regulations at 42 CFR part 493.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of analyzer operator manuals, laboratory environmental records, and interview with facility personnel, the laboratory failed to monitor the humidity of the operating environment for 4 of 4 months reviewed between January 1, 2018 and May 9, 2018. The findings included: 1. Based on review of analyzer operator manuals, the following equipment have relative humidity requirements for the operating environment: Microm HM 525 Cryostat - "Operating Conditions 5 degrees Celsius to 35 degrees Celsius at a max relative humidity of 60 percent (page 14 of the operator's manual) Vitros 5600 automated chemistry analyzer -15 percent to 75 percent humidity between the temperatures of 15 degrees Celsius and 25.6 degrees Celsius, decreasing to 15 - 60 percent relative humidity for temperatures between 25.6 and 30 degrees Celsius. 2. Based on review of laboratory environmental records for 4 of 4 months reviewed between January 1, 2018 and May 9, 2018, the laboratory did not monitor the relative humidity in the operating environment. 3. In an interview at 11:00 hours on 5/9/2018 in the office, the General Supervisor stated the laboratory had previously

	monitored relative humidity levels of the operating environment but had ceased documenting humidity levels when the previous chemistry analyzer was removed.
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 quality control records, laboratory policies and procedures, and interview with facility personnel, the laboratory failed to evaluate all patient test results since the last acceptable control run when results of quality control failed to meet laboratory established acceptability criteria The findings included: 1. Based on review of quality control records and corrective action documentation, the laboratory documented the following corrective actions for quality control material tested on the Vitros 5600 automated chemistry analyzer: Analyte: FSH Quality Control: Immunoassay Plus Bio-Rad Level 3 Run: 30.09 SDI: -3.14 - unacceptable Time: 4/3 /2018 at 07:19 hours Corrective action: "Will repeat." Analyte: FSH Quality Control: Immunoassay Plus Bio-Rad Level 3 Run: 30.96 SDI: -2.26 - unacceptable Time: 4/3 /2018 at 08:41 hours Corrective action: "last pack of ths reagent lot number has a low volume and QC low bias, will cal new lot number 2460 and put into use. Analyte: FSH Quality Control: Immunoassay Plus Bio-Rad Level 3 Run: 31.60 SDI: -1.61 - QC is acceptable Time: 4/3/2018 at 09:26 hours Corrective action: "post cal result, new lot number 2460 There is no documentation of evaluating patient results of specimens tested since the last acceptable quality control run on 4/2/2018 at 09:28 hours. Corrective actions required replacing a FSH reagent and recalibrating in order to obtain a quality control value within the laboratory's established acceptability criteria. Analyte: Prealbumin Quality Control: Immunology QC Level 1 Run: 15.990 SDI: 3.10 - unacceptable Time: 4/5/2018 at 07:32 hours Corrective action: "Will repeat." Analyte: Prealbumin Quality Control: Immunology QC Level 1 Run: 16.146 SDI: 3.58 - unacceptable Time: 4/5/2018 at 08:54 hours Corrective action: "Will repeat with fresh cup of QC" Analyte: Prealbumin Quality Control: Immunology QC Level 1 Run: 15.854 SDI: 2.68 - unacceptable Time: 4/5/2018 at 09:09 hours Corrective action: "Due to high bias and L1 QC failure, will re-cal assay and repeat QC" Analyte: Prealbumin Quality Control: Immunology QC Level 1 Run: 15.099 SDI: 0.36 - QC is acceptable Time: 4/5/2018 at 09:43 hours Corrective action: "post cal result, re-cal due to L1 high bias and L1 QC failure, same gen lot number 15 slash 6219" There is no documentation of evaluating patient results of specimens tested since the last acceptable quality control run on 4/4/2018 at 07:36 hours. Corrective actions required recalibrating the Prealbumin assay in order to obtain a quality control value within the laboratory's established acceptability criteria. 2. Based on review of the laboratory's quality control policy "Technical Procedure Manual West Texas Medical Associates Chemistry Quality Control" states the following: "Interpretation: Reporting Results" "1. Patient results may be reported after the quality control run is successful. 2. Patient results may not be reported if the quality control material does not recover the values expected. Hold patient specimens and notify the patient

	Providers if there will be a delay in patient testing." The quality control policy does not include instructions for evaluating 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 as required at 42 CFR part 493. 1282(b)(2). 3. In an interview at 16:00 hours on 5/9/2018 in the laboratory, the General Supervisor stated the laboratory never released patient results until quality control was within acceptable limits but had not routinely evaluated patients tested since the last acceptable control value when quality control results failed to me the laboratory's established acceptability criteria.