Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0488551	03/02/2021
Name of Provider or Supplier	**Street Address, City, State**	
Waco Mclennan Co Public Hlth Dist Lab	225 W Waco Dr, Waco, 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
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Review of proficiency testing records, patient test records and interview of facility personnel found the laboratory failed to test proficiency testing specimens in the same manner as it tests patient specimens that produce a reactive Rapid Plasma Reagin (RPR) result in six of six testing events in 2019 and 2020. The findings included: 1. Review of the Medical Laboratory Evaluation (MLE) proficiency testing records for 2019 and 2020 found no responses or graded results for quantitative RPR results in six of six testing events. 2. Review of patient test records for 2021 found the laboratory performed quantitative RPR testing on patient samples producing a reactive RPR result, and would report this titered result to the provider. 3. Interview of testing person one listed on the CMS report 209 Laboratory Personnel Report conducted on March 2, 2021 at 09:59 AM confirmed that the laboratory did not perform quantitative procedures on proficiency testing specimens as they do on patient specimens.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially

	available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Review of the laboratory policy titled RPR control procedure, quality control logs and interview of facility personnel, found the laboratory failed to follow their own procedure for verifying the volume delivered by the dispensing needle (used for delivery of the Rapid Plasma Reagin (RPR) antigen) met their own requirements. The findings included : 1. Review of the RPR Control procedure found on page 1 "The dispensing needle for the antigen is to be tested weekly by the following method: a. Attach the hub of the needle to the tip of a 1 ml pipette. b. Fill the pipette and count the number of drops delivered in 0.5 ml. There should be 30 +/- 1 drop per 0.5 ml. c. Record results on the RPR Quality Control Log to be maintained in the laboratory at all times." 2. Review of the RPR Quality Control Logs found the column for needle volume dispensing to be pre-filled with a value of "60" each day. 3. Interview of testing person one on the CMS report 209 Laboratory Personnel Report conducted on March 2, 2021 at 10:55 AM found the laboratory does not check the antigen needle volume delivery weekly as defined in their own procedure.