Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0488551	11/29/2022
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
D0000	An onsite survey conducted November 29, 2022 found the laboratory in compliance with 42 CFR Part 493, Requirements for Laboratories.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, proficiency testing records from 2021, and interview with the Laboratory Manager, the laboratory failed to assess the accuracy of wet mount and potassium hydroxide (KOH) microscopic procedures twice annually for one of one year in 2021. Findings included: 1. A review of the laboratory's policy "Proficiency Testing Review" stated "Proficiency testing must be performed for all tests of moderate complexity". 2. A review of the laboratory's proficiency testing records from 2021 found the laboratory was not enrolled in PT (proficiency testing) or a twice annual verification program for Wet Mount or KOH preparations. 3. In an interview on 11/29/2022 at 12:15 PM, the Laboratory Manager confirmed the laboratory was neither enrolled in a proficiency testing program nor did the laboratory have a method in place to verify the accuracy of the test results at least twice a year.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, competency assessment records, and interview with the Laboratory Manager, the Technical Consultant failed to assess competency for one of one testing personnel performing wet mount and potassium hydroxide (KOH) microscopic procedures for 2021. The findings included: 1. The laboratory's policy titled "Testing Personnel Competency Procedure" stated "Competency evaluations of laboratory testing personnel should occur at least semiannually during the first 12 months the individual tests client specimens. Thereafter, competency evaluations must be performed at least annually." 2. Based on review of competency assessment records, the Technical Consultant did not document annual competency for wet mount and KOH procedures for the Laboratory Manager, who served as the primary testing personnel for these tests in 2021. The annual volume for these tests was listed as 20 tests on the survey paperwork. 3. In an interview on 11/29/2022 at 12:15 PM, the Laboratory Manager confirmed the Technical Consultant had not performed a competency assessment for wet mount and KOH preparations in 2021.