Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0660409	01/24/2024
Name of Provider or Supplier	**Street Address, City, State**	
San Antonio Metropolitan Hlth Dist Lab	2303 Se Military Drive, Bldg 533, San Antonio, 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
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 upon observations, review of policies and procedures, manufacturer's instructions and interview of facility personnel, the laboratory failed to follow the manufacturer's instructions for verifying the dispense volume of the needle used for delivering the reagin antigen used when testing patient samples for RPR (Rapid Plasma Reagin) in 2022 and 2023. The findings included: 1. Based upon observations made during the demonstration of the RPR antigen needle check by testing person 6 conducted January 23, 2024 at 1:21 PM, the laboratory used a serological pipette to measure the volume of 31 drops of RPR antigen dispensed into a secondary container. The volume exceeded the expected 0.5 ml. 2. Review of the laboratory's procedure titled ASI RPR CARD TEST PROCEDURE FOR SYPHILIS found at 6.6: " The needle drops must be within 30 +/- 1 drop/0.5 ml. This can be done by dispensing 29-30 drops in the reagent vial with a 1 ml serological pipette. The volume should be approximately 0.5 ml." 3. Review of the manufacturer's instructions found under the heading HANDLING AND PROCEDURAL NOTES: "1. In order to obtain reliable and consistent results, the instructions in the package insert must be strictly followed. Do not modify the handling and storage conditions for reagents or samples. 4. The needle should deliver 60 + 2 drops of antigen suspension per milliliter when held in a vertical position. To perform accuracy check on the needle, attach the needle to a 1 or 3 ml syringe. Fill the syringe with the antigen suspension and, holding the syringe in a vertical position, count the number of drops delivered in 0.5 ml. The needle is considered satisfactory if 30 + 1 drops are obtained in 0.5 ml." 4. During interview of

	the Technical Consultant conducted January 23, 2024 at 1:44 PM, she confirmed that the laboratory did not verify the needle dispense volume as per the manufacturer's instructions.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) 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)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based upon observations, review of policies and procedures, manufacturer's instructions and interview of facility personnel, the laboratory director failed to ensure that testing personnel followed the manufacturer's instructions for verifying the volume of the needle used for dispensing the reagin antigen used when testing patient samples for RPR (Rapid Plasma Reagin) in 2022 and 2023. (See D 5411)
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based upon review of policies and procedures, proficiency testing records and interview of the facility personnel, the laboratory director failed to ensure there was a written procedure for performing twice annual accuracy assessment of results for Darkfield microscopy identification of Treponema pallidum spirochetes and direct smear wet mounts for Trichomonas in 2022 and 2023. The findings included: 1. Review of policies and procedures found no written procedure for the twice annual accuracy assessment of results for which there was not a CMS approved proficiency testing program. 2. Review of records provided for the assessment of accuracy of results for darkfield microscopy and wet mount examinations, found that some of the records were kept in the personnel files and some were kept in patient result notebooks. 3. During interview of the Technical Consultant conducted January 24, 2024 at 12:25 PM, she confirmed there was no written procedure for performing twice annual accuracy assessments available.