Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0890077	01/15/2025
Name of Provider or Supplier	**Street Address, City, State**	
Austin Public Health	15 Waller St, Austin, 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	The laboratory was found NOT to be in compliance with the CLIA regulations found at 42 CFR 493 CLIA requirements. The condition not met was: D5012 - 42 C.F.R. 493.1207 Condition: Syphilis serology.
D5012	SYPHILIS SEROLOGY CFR(s): 493.1207 If the laboratory provides services in the subspecialty of Syphilis serology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on manufacturer's instructions, policies and procedures, observation, function check, testing logs, test reports, presurvey paperwork, and interview, the laboratory failed to meet the requirements for the Specialty when they failed to follow the manufacturer's instructions for verifying the dispense volume of the needle used for delivering the carbon antigen when testing 12 of 12 patient samples for the RPR (Rapid Plasma Reagin) card test on January 15, 2025. See D5431.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of competency evaluations, laboratory policies and procedures, and interview, the laboratory failed to assess competency for one of one clinical consultant

	and one of one technical consultant. Findings follow. A. Review of competency evaluations showed none for the positions of clinical consultant and technical consultant. Competency evaluations were requested on January 15, 2025 at 1040 hours but not provided. B. Review of the laboratory's policies and procedures showed no policy and procedure for competency evaluations. A policy and procedure was requested on January 15, 2025 at 1540 hours in the office but not provided. C. Interview with testing personnel #1 (as listed on the CMS Form 209) on January 15, 2025 at 1040 hours in the office confirmed they had not been performed.
D5219	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(2) (c)(2) Any test or procedure listed in subpart I of this part for which compatible proficiency testing samples are not offered by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on review of accuracy assessments, laboratory policies and procedures, presurvey paperwork, and interview the laboratory failed to access at least twice per year accuracy of its darkfield microscopy for the identification of Treponema pallidum testing for two of two years (four of four events) reviewed. Findings follow. A. Review of the laboratory's accuracy assessment records from 2023 and 2024 showed no accuracy assessments for the darkfield microscopy for the identification of T. pallidum. B. Review of the laboratory policies and procedures showed none for accuracy assessments for darkfield microscopy for T. pallidum. The policy and procedure was requested on January 15, 2025 at 1540 hours in the office but not provided. C. Review of the presurvey paperwork titled Annual Test Volume & Proficiency Testing (PT) Programs Worksheet showed "peer review" in the column for PT Program and 36 test per year for darkfield microscopy. D. Interview with testing personnel #1 (as listed on the CMS Form 209) on January 15, 2025 at 1305 hours in the office confirmed accuracy assessments were not performed.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) (a)(2) Function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturers established limits before patient testing is conducted. (b) 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 do the following: This STANDARD is not met as evidenced by: Based on manufacturer's instructions, laboratory policies and procedures, observation, function checks, testing logs, test reports, presurvey paperwork, and interview, the laboratory failed to follow the manufacturer's instructions for verifying the dispense volume of the needle used for delivering the carbon antigen when testing 12 of 12 patient samples for the RPR (Rapid Plasma Reagin) card test on January 15, 2025. Findings follow. A. Review of the package insert for the ASI (Arlington Scientific Inc) RPR card test for syphilis, 10/1997, 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 modified the handling and storage conditions for reagents or samples. 2. ASI RPR test cards are plastic coated and specifically designed to be used with the RPR antigen. In handling, take care not to fingermark the card areas, as this may result in an oily deposit and improper test result. When spreading specimen within the confines of the circle area, avoid scratching the card with the stirrer pipets. If the specimen does not spread in the test area or spreads outside the test area, use another test circle. 3. The needle assembly must be thoroughly washed in distilled or deionized water and air-dried after each shift. Do not wipe the needle dry. Place the needle back into the plastic sleeve. Do not remove bottle tip when washing the needle assembly. Let the assembly air dry. Before next use, make sure that no large water droplets remain in the dropping bottle by shaking the bottle and squeezing it. 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, attached the needle to a 1 or 3 mL syringe. Fill the syringe with antigen suspension and, holding the syringe in a vertical position, count the number of drops delivered in 0.5 mL. The needle is considered a satisfactory if 30 +/- 1 drops are obtained in 0.5 mL..." B. Review of the laboratory policy and procedure titled ASI-RPR Test Procedure, effective 12/03/2003, under XII. Procedure Notes/Sources of Error stated, "d. 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. The results are recorded on a daily basis on the RPR Quality Control Log." C. During demonstration of the RPR antigen needle drop check by the technical consultant /testing person #2 (as listed on the CMS Form 209) conducted January 15, 2025 at 1355 hours in the laboratory dispensed 26 drops of 0.5 mL carbon antigen vertically into the vial. The result of the test was 52 drops in 1 mL after multiplying 26 times 2: the needle drop check failed. He then repeated the needle drop check two more times and obtained 28 drops both times in 0.5 mL of carbon antigen; the result was multiplied by 2 to obtain 56 drops in 1 mL: the needle drop check failed. D. Review of the RPR Quality Control Log from Feb 2023 to January 15, 2025 showed 60 was documented for the needle drop check for 486 out of 486 days reviewed. E. Review of the Communicable Disease Laboratory Accession/Testing Log showed 12 patients had been performed on January 15, 2025 as listed by account number: 1. 64197 2. 531401 3. 505931 4. 142476 5. 382943 6. 147894 7. 144809 8. 552183 9. 135588 10. 92116 11. 551897 12. 107369 F. Review of the test reports for the 12 patients performed on January 15, 2025 showed the 12 patients had been reported. G. Review of the presurvey paperwork titled Annual Test Volume & Proficiency Testing (PT) Programs Worksheet showed a test volume of 8638 per year. H. Interview with the technical consultant/testing person #2 on January 15, 2025 at 1355 hours in the laboratory confirmed the needle did not dispense the correct volume of carbon antigen.