

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0890077	(X3) Date Survey Completed 09/11/2026
Name of Provider or Supplier Austin Public Health	Street Address, City, State 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 Austin Public Health laboratory was found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780, CLIA requirements for laboratories as a result of a recertification survey on 09/09/2026 and recertification is recommended. Standard level deficiencies were cited.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: I. Based on review of the laboratory's textbook procedure, the laboratory's policy and procedure, pre-survey documents, and interview, the laboratory failed to follow textbook procedure for performing Wet Preps used for the identification of trichomonas, clue cells, and yeast for two of two years reviewed. Findings follow. A. Review of the laboratory's textbook procedure from Diagnostic Microbiology, 11th Edition, 2002, Chapter 61, at Lower Genital Tract Infections stated, "Because T. vaginalis may be present in urethral discharge, material for culture should be collected by swab as just described and another specimen collected on a swab and placed into a tube containing 0.5 mL of sterile physiologic saline. This specimen should be hand-delivered to the laboratory immediately. Direct wet mounts and cultures for T. vaginalis can be performed from this second specimen." B. Review of the laboratory's policy and procedure titled, KOH/Wet Prep Procedure, revised 08/13/2013, under Specimen stated, "a. The appropriate specimen is a vaginal or cervical swab suspended in 1/2 to 1 ml saline." The volume of saline delivered is up to twice the volume required by the textbook reference. C. Review of the pre-survey document Annual Test Volume & Proficiency Testing Programs Worksheet, showed an

estimated 1892 Wet Preps were performed annually. D. Interview with technical consultant/ testing personnel #1, on the CMS Form 209, on September 09, 2026 at 1315 hours in the laboratory acknowledged the nurse will bring a tube with the swab into the laboratory and the tech will add about 1 mL using a squeeze bottle to deliver an estimated amount of 1 mL by "eye-balling" the volume dispensed into the vial. II. Based on review of the laboratory's policy and procedure, preventive maintenance schedule, pipette calibration checks, and interview, the laboratory failed to follow its own policy and procedure for annual pipette calibration checks in 2025 for one of two years reviewed. Findings follow. A. Review of the laboratory's policy and procedure titled Laboratory Equipment Preventative Maintenance, revised 08/17/2006, stated, "a. All instruments within the Communicable Disease Laboratory will have preventative maintenance done per manufacturer's guidelines. b. All preventative maintenance will be recorded, and records will be kept for the life of the instrument. c. Schedule for Preventative Maintenance is per equipment found in the Preventative Maintenance Manual." B. Review of the Preventive Maintenance Schedule, rev 09/17/2020, under Annually stated, "4. MLA 50 microliter pipettes- Medical Equipment Services to perform calibration checks." C. Review of pipette calibration checks for 2025 and 2026 for the MLA 50 uL and 25 uL pipettes showed none for 2025. Calibration checks for 2025 were requested on September 9, 2026 at 1430 hours in the office but not provided. D. Email from the public health supervisor on September 11, 2026 at 0955 hours confirmed the findings. KEY: ml = milliliter uL = microliter

D5805

TEST REPORT
CFR(s): 493.1291(c)

(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on review of patient test reports, pre-survey paperwork, and interview, the laboratory failed to provide the reported date on 12 of 12 test reports reviewed from March 2025 - July 2026. Findings follow. A. Review of 12 randomly selected EMR test reports from March 2025 - July 2026 showed the test reports were all missing the date reported as listed by Date of Service: Date of Service 1. 03/17/2025 2. 03/26/2025 3. 03/28/2025 4. 07/03/2025 5. 07/09/2025 6. 10/30/2025 7. 10/31/2025 8. 01/27/2026 9. 04/13/2026 10. 04/23/2026 11. 07/20/2026 12. 07/23/2026 B. Review of the presurvey paperwork titled CMS Form 116 showed an estimated annual test volume of 22179. C. Interview with the nurse practitioner on September 9, 2026 at 1515 hours in the office confirmed the findings after a review of the records. KEY: EMR = Electronic Medical Record