Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0054765	06/10/2025
Name of Provider or Supplier	**Street Address, City, State**	
Texas State University	298 Student Center Drive, San Marcos, 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 surveyed and found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780, and recertification is recommended. Standard level deficiencies were cited.
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) (b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure, proficiency testing records and interview, the laboratory failed to test proficiency testing (PT) samples the same number of times that it routinely tests patient samples for three out of three microscopy events reviewed in 2024 and 2025. Findings follow. A. Review of the laboratory's policy and procedure titled Proficiency Testing, revised 06/2025, did not address the number of times a sample should be tested or how the specimen should be handled. B. Review of the American Proficiency Institute (API) PT records from the second and third events of 2024 and the first event in 2025 showed PT results were obtained for microscopy results from testing personnel #1, 2, and 3 (as listed on the CMS Form 209) for all of the microscopy tests included in the three testing events. The microscopy portions in the Hematology event included the manual differential of the Complete Blood Count (CBC), urine microscopy, and wet prep with and without potassium hydroxide (KOH). C. Interview with the general supervisor/ technical consultant #2 (as listed on the CMS Form 209) on June 10, 2025 at 1025 hours in the office confirmed "everyone looked at the manual differential, microscopic urinalysis, and wet prep pictures."
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, interview, test reports, observation, and pre-survey documents, the laboratory failed to follow textbook procedure for performing Wet Preps used for the identification of trichomonas, clue cells, and yeast when they added vortexing the sample for two of two years reviewed. Findings follow. A. Review of the laboratory's textbook procedure Brunzel, Nancy A. Fundamentals of Urine and Body Fluid Analysis, W.B. Saunders Company, 1994, pp 259-260. Under Clue Cells and Gardnerella Vaginalis stated, "Although clue cells are not often present in a urine specimen, they are readily recovered from a vaginal swab. The physician collects a swab of the vaginal mucosa, which is then transported to the laboratory. The swab is placed into approximately 0.5 mL of normal saline and agitated to suspend the vaginal secretions in the solution. For the visualization of formed elements, a wet mount of the saline suspension is prepared using a microscope slide and coverslip. The wet mount is observed for the presence of trichomonads, clue cells, bacteria, yeast, hyphae, and other fungal cells using both low- and high-power magnification. Clue cells are often readily apparent in these wet preparations. A KOH preparation for yeast, hyphae, and other fungal cells destroys clue cells and trichomonads. When KOH is added and a distinctly foul, fishy odor develops, however, it is indicative of G. vaginalis and an anaerobic counterpart (often Mobiluncus curtisii)." B. Review of the laboratory's policy and procedure titled, Wet Mount, reviewed 12/17/2018, under Test & Quality Control Procedure stated, "Gently mix the specimen and place two drops on opposite sides of a plain microscope slide. Add one drop on 10% KOH to one side. Place a coverslip on both ends, being careful to avoid trapping air bubbles under the coverslip..." C. Interview with testing personnel #2 on June 10, 2025 at 1350 hours in the laboratory acknowledged she vortexed the sample for 5-10 seconds before analyzing. Interview with the general supervisor/ technical consultant #2 on June 10, 2025 at 1352 hours in the laboratory confirmed the procedure of vortexing the sample for 5-10 seconds before analyzing. Vortexing the sample could disrupt the cell membranes of the trichomonas. D. Random review of test reports showed the test was performed on 1. 05/07/2025 2. 05/13/2025 3. 05/16/2025 4. 05/20/2025 5. 06/02 /2025 E. Surveyor observed on June 10, 2025 at 1615 hours in the office one positive trichomonas result in roughly 50 test reports. F. Review of the pre-survey document Annual Test Volume & Proficiency Testing Programs Worksheet showed an estimated 1744 Wet Preps were performed annually. II. Based on review of the laboratory's textbook procedure, the laboratory's policy and procedure, interview, test reports, and pre-survey documents, the laboratory failed to follow textbook procedure for performing Wet Preps used for the identification of trichomonas, clue cells, and yeast when they did not standardize the amount of saline in the tube the swab was inserted into for two of two years reviewed. Findings follow. A. Review of the laboratory's textbook procedure Brunzel, Nancy A. Fundamentals of Urine and Body Fluid Analysis, W.B. Saunders Company, 1994, pp 259-260. Under Clue Cells and Gardnerella Vaginalis stated, "Although clue cells are not often present in a urine specimen, they are readily recovered from a vaginal swab. The physician collects a swab of the vaginal mucosa, which is then transported to the laboratory. The swab is placed into approximately 0.5 mL of normal saline and agitated to suspend the vaginal

	secretions in the solution. For the visualization of formed elements, a wet mount of the saline suspension is prepared using a microscope slide and coverslip. The wet mount is observed for the presence of trichomonads, clue cells, bacteria, yeast, hyphae, and other fungal cells using both low- and high-power magnification. Clue cells are often readily apparent in these wet preparations. A KOH preparation for yeast, hyphae, and other fungal cells destroys clue cells and trichomonads. When KOH is added and a distinctly foul, fishy odor develops, however, it is indicative of G. vaginalis and an anaerobic counterpart (often Mobiluncus curtisii)." B. Review of the laboratory's policy and procedure titled, Wet Mount, reviewed 12/17/2018, under Specimen Collection & Preparation stated, "The provider collects vaginal sample on a swab that is inserted into a 20x75 mm tube with 0.85 NaCl and is delivered to the laboratory." C. Interview with the general supervisor/ technical consultant #2 on June 10, 2025 at 1400 hours in the laboratory confirmed the nurse was responsible for adding the saline to the tube and the volume added was not a prescribed amount. D. Random review of test reports showed the test was performed on 1. 05/07/2025 2. 05 /13/2025 3. 05/16/2025 4. 05/20/2025 5. 06/02/2025 E. Review of the pre-survey document Annual Test Volume & Proficiency Testing Programs Worksheet showed an estimated 1744 Wet Preps were performed annually.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, the laboratory policy and procedure, maintenance logs, and interview, the laboratory failed to perform monthly maintenance on the Beckman Coulter DxH 520 analyzer for Complete Blood Counts (CBCs) for eight out of 12 months reviewed. Findings follow. A. Review of the Beckman Coulter DxH 520 Instructions for Use, March 2019, Chapter 12 Cleaning Procedures under When, Why, and How to Perform Each Cleaning Procedure at Table 12.1 Matrix of Frequency for Cleaning Procedures stated, 1. "Procedure Performing a Bleach Cycle Purpose To Remove Clogs... Frequency Every 1000 cycles or monthly, whichever comes first" 2. And under "Procedure Cleaning the WBC Bath filter Purpose To remove buildup and deposits trapped by the filter Frequency Monthly" B. Review of the laboratory's policy and procedure titled Beckman Coulter DxH 520 under Maintenance Schedule/Cleaning Procedures stated, "Monthly or every 1,000 cycles Bleach cycle Monthly Cleaning the WBC Bath Filters" "Which ever comes first" is missing from the procedure which would require the maintenance at least monthly. C. Review of the DxH500 Instrument Maintenance Checklist from June 2024 - May 2025 showed no documentation of the monthly maintenance on the following eight months: 1. June 2024 Perform Bleach Cycle Clean the WBC Bath Filter 2. July 2024 Clean the WBC Bath Filter 3. August 2024 Perform Bleach Cycle 4. November 2024 Perform Bleach Cycle Clean the WBC Bath Filter 5. December 2024 Perform Bleach Cycle Clean the WBC Bath Filter 6. February 2025 Clean the WBC Bath Filter 7. March 2025 Perform Bleach Cycle Clean the WBC Bath Filter 8. May 2025 Clean the WBC Bath Filter D. Interview with the general supervisor/ technical consultant #2 (as listed on the CMS Form 209) on June 10, 2025 at 1225 hours in the office acknowledged she thought the service was required every 1000 cycles.

D6051	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v) (b)(8)(v) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure, competency evaluations, and interview, the technical consultant failed to assess test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples for one out of six testing personnel competencies reviewed for moderately complex testing in 2023 and 2024. Findings follow. A. The laboratory's policy and procedure for competency evaluations was requested on June 10, 2025 at 1030 but not provided. B. Review of competency evaluations showed the following testing personnel was missing test performance through previously analyzed specimens, internal blind testing samples, or external proficiency testing samples: 1. Testing personnel #4 (TP#4) (as listed on the CMS Form 209) from 2024 was missing the Complete Blood Count (CBC) on the Beckman Coulter DxH520, manual differential, microscopic urinalysis, and wet prep. The Competency Assessment from 10/25/2024 showed "N/A" for "Accurate test performance has been proven by external Proficiency Testing. ([TP#4] wasn't scheduled to work during any of the PT events)." C. Interview with the general supervisor/ technical consultant #2 on June 10, 2025 at 0950 hours in the office confirmed the findings.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) (b)(9) Thereafter, evaluations must be performed at least annually This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure, competency evaluations and interview, the technical consultant failed to evaluate the performance of individuals performing moderately complex testing at least annually after the first year the individual tested patient specimens for one of two testing personnel reviewed in 2023. Findings follow. A. The laboratory's policy and procedure for competency evaluations was requested on June 10, 2025 at 1030 but not provided. B. Review of competency evaluations from 2023 and 2024 for moderately complex testing revealed none were performed in 2023 for testing personnel #4 (as listed on the CMS Form 209). C. Interview with the general supervisor/ technical consultant #2 on June 10, 2025 at 0955 hours in the office confirmed the findings and stated she was a PRN employee.