

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0659922	(X3) Date Survey Completed 01/17/2025
Name of Provider or Supplier Pathology Assocs Of North Texas Pa	Street Address, City, State 1209 Brook Avenue, Wichita Falls, 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 to be in compliance with 42 CFR Part 493, Requirements for Laboratories as a result of a recertification survey on 1/17/2025.
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Review of the laboratory provided test menu, laboratory policy, laboratory documentation, and confirmed in interview, the laboratory failed to follow their policy for the monitoring of contamination on the panther system performing molecular testing for one of two years reviewed in 2023 and 2024. The findings included: 1. Review of the laboratory provided test menu included the following molecular tests performed on the Panther System: CT/GC Trichomonas HPV HPV Genotype 18/45 2. Review of the laboratory policy titled "Contamination Monitoring Protocol For The Panther System", included the following instruction: "To monitor for laboratory contamination, the following procedure may be performed using the APTIMA Unisex Swab Collection kit for Endocervical and Male Urethral Swab Specimens: 1. Label swab transport tubes with number corresponding to the areas to be tested. 2. Remove the specimen collection swab (blue shaft swab with green printing) from its packaging, wet the swab in the swab transport medium, and swab the designated area using a circular motion. 3. Immediately insert the swab into the transport tube. 4. Carefully break the swab shaft at the score line: use care to avoid splashing of the contents. 5. Recap the swab transport tube tightly. 6. Repeat Steps 2 to 5 for each area to be swabbed. 7. Test samples with the APTIMA Trichomonas vaginalis Assay and /pr CT/GC Combo Assay on the Panther System. 8. Further investigation should be</p>

performed if any samples yield a positive result. 9. For additional PATHER System-specific contamination monitoring information, contact Gen-Probe Technical Support. 10. Monitoring should take place at least every six months. Interpretation: Results should be Negative." Surveyor asked how often the laboratory performed the contamination checks, and testing personnel (TP) 10 stated they performed the test every six months, typically in April and October. 3. Review of the contamination check records for 2024 included the following six areas in the laboratory and preparation areas swabbed for contamination checks: Vortex Phone Light Switch Pipette Door Handle MTU Drawer Surveyor asked for the 2023 documentation, and none could be provided. 4. In an interview on 1/17/2025 at 11:26 in the reception area, TP 10 stated the laboratory failed to perform the contamination check for the Panther System in 2023 as the laboratory policy required. KEY: CT/GC - Chlamydia, Gonorrhea HPV - Human Papilloma Virus

D5617

CYTOLOGY
CFR(s): 493.1274(b)(2)

(b)(2) Effective measures to prevent cross-contamination between gynecologic and nongynecologic specimens during the staining process must be used.

This STANDARD is not met as evidenced by:
Based on review of laboratory policy, laboratory annual statistics, and confirmed in interview, the laboratory failed to ensure effective measure to prevent cross-contamination between gynecologic and nongynecological specimens during the staining process were followed for documentation reviewed in 2023 and 2024 for a total of 18,301 cytology specimens processed. The findings included: 1. Review of the laboratory policy binder titled "Pathology Associates Quality Manual", subsection "Cross Contamination Control" stated the following: "Samples with a high potential for cross-contamination must be stained separately from all other specimens. Non-gyn and FNA specimens are stained in separately from Pap smears at the end of the day. Since we have a single staining setup solutions should be changed between gynecological and non-gynecologic specimens." 2. Review of the laboratory annual statistics for 2020 and 2024 included the following information: 2023 Cytology Annual Report Total Number Cytology Cases Examined 9374 Non-Gynecologic Cases - 332 Fine Needle Aspiration - 342 Gynecologic Cases - 8700 2024 Cytology Annual Report Total Number Cytology Cases Examined 8927 Non-Gynecologic Cases - 431 Fine Needle Aspiration - 302 Gynecologic Cases - 8194 3. Surveyor asked for documentation in the changing of stains after non gynecologic specimens to prevent the potential cross contamination to gynecologic specimens and none could be provided. 4. In an interview on 1/17/2024 at 11:45 hours, in the reception room, testing personnel (TP) 10 confirmed that the laboratory did not change stains between non-gynecological specimens and gynecological specimens.