

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0483328	(X3) Date Survey Completed 09/07/2023
Name of Provider or Supplier Pathology Associates Of Tyler, Pa	Street Address, City, State 1726 South Beckham, Tyler, 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	An onsite survey conducted 09/07/2023 found the laboratory in compliance with 42 CFR Part 493, Requirements for Laboratories.
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the manufacturer's instruction for use, laboratory staining documents, patient final reports, and confirmed in an interview, the laboratory failed to follow the manufacturer's instructions for the staining of slides on the ThinPrep staining system for 85 of 85 patients who were processed over the stain limit for two instances reviewed from December 2022 to June 2023. The findings included: 1. Review of the "ThinPrep Stain User's Manual", section "Procedure Notes For Automated Staining" had the following statement: "Change all solutions when the number of slides equals 1 slide for every 1 mL of bath volume, or once a week, which ever comes first. (For example if your bath volume is 650 mL, then change the bath after 650 slides, or once a week, which ever comes first.)" 2. Review of the laboratory "Thin Prep Stain Maintenance" had the following instructions at the top of the sheet: "All solutions changed *(at or before 320 slides stained)" At 11:25 hours, in the laboratory, the general supervisor (GS) demonstrated that the bath volume of the stain held 320 mL. 3. Review of the laboratory "Thin Prep Stain Maintenance" for December 2022 through June 2023 had the following batch staining occurrences where the slides stained exceeded 320 without a change of stains: December 2022: 12 /6/2022: Starting Slide Count:308 Slides stained: 16 Ending Slide Count: 324 16 patient slides were stained on 12/6/2022 to include the following 5 patient accessions:</p>

TP22-6422 TP22-6423 TP22-6425 TP22-6432 TP22-6437 June 2023: 6/28/2023: Starting Slide Count: 315 Slides stained: 31 Ending Slide Count: 346 31 patient slides were stained on 6/28/2023 to include the following 5 patient accessions: TP23-2677 TP23-2710 TP23-2730 UTP23-662 UTP23-664 6/29/2023: Starting Slide Count: 346 Slides stained: 22 Ending Slide Count: 368 22 patient slides were stained on 6/29/2023 to include the following 5 patient accessions: TP23-2731 TP23-2736 TP23-2740 UTP23-666 UTP23-670 6/30/2023: Starting Slide Count: 368 Slides stained: 33 Ending Slide Count: 401 33 patient slides were stained on 6/30/2023 to include the following 5 patient accessions: TP23-2736 TP23-2748 TP23-2760 TP23-2766 UTP23-674 4. In an interview on 9/7/2023 at 10:50 hours, in the office, the GS confirmed that the stain had not been changed at or before 320 slides for the above instances, as required by the manufacturer.