

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0219659	(X3) Date Survey Completed 11/27/2023
Name of Provider or Supplier Pathology Associates Laboratories Pc	Street Address, City, State 5601 Loch Raven Blvd Pob Ste 102, Baltimore, MD	
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
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the laboratory director (LD) and quality staff (QS), the laboratory did not maintain a record of the reagents used for histopathology tissue processing and slide preparation and staining. Findings: 1. The laboratory processed biopsy tissue and prepared and stained tissue slides for histopathology evaluation. 2. Slides were stained with hematoxylin and eosin (H&E) and specialty stains including Diff-Quik and periodic acid Schiff with Alcian Blue (PAS/AB). 3. The quality control section of the Diff-Quick and PAS/AB procedures stated to "check the reagents for expiration date", but there was no policy or procedure to document the lot number and expiration date of the stains used on patient slides. 4. During the survey on 11/27/2023 at 1:05 PM, the LD and QS confirmed that the laboratory did not have policies or procedures to document or retain the lot numbers, expiration dates, and dates in use for the reagents used for processing biopsy tissue and preparing and staining tissue slides.</p>