Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2320931	02/18/2026
Name of Provider or Supplier	**Street Address, City, State**	
Cutting Edge Histology Llc	18207a Flower Hill Way, Gaithersburg, 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
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: Based on review of the procedure manual and interview with the testing personnel (TP), the laboratory did not perform instrument maintenance or change/filter staining reagents with the frequency that was defined in the procedure manual. Findings: 1. The "Quality Control" procedure stated that "PM [preventive maintenance] of equipment (Tissue Processors, embedding center, microtomes, water baths, Leica Autostainer, coverslipper, DAKO immunostainer are performed yearly by qualified specialists." 2. Records showed that the last instrument PM was performed on 11/11 /2024. 3. The "Staining" section of the "Procedure to Prevent Cross Contamination of Specimens" stated to "Change or filter reagents before each day of use to prevent floaters." 4. The "H&E [Hematoxylin and Eosin] Stain Rotation Log" showed that all staining reagents were not changed or filtered each day of use. 5. During the exit interview on 02/18/2026 at 1:30 PM, the TP confirmed that the instrument PM and changing/filtering of staining reagents were not performed with the frequency defined in the procedures due to the current volume of patient testing.