

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D0099096	(X3) Date Survey Completed 07/01/2025
Name of Provider or Supplier Yale Dermatopathology Laboratory	Street Address, City, State 15 York Street Lci 504-505, New Haven, CT	
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	<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: Based on surveyor observation, record review and staff interview the laboratory failed to provide an updated procedure manual for the Hematoxylin and Eosin (H&E) staining in the subspecialty of Dermatopathology. Findings include: 1. Surveyor observation on 7/1/2025 at 11:50 AM of the Sakura Prisma Stainer, "Program-IFU#1" revealed the following for Steps 2 through 22: Step Solution Name Time (min:sec) 2 Drying Station 01:30 3 Xylene 01:30 4 Xylene 01:00 5 Alcohol 100% 01:30 6 Alcohol 100% 01:00 7 Alcohol 95% 01:00 8 Wash Station 01:00 9 Hematoxylin 02:30 10 Wash Station 01:00 11 Differentiator 01:00 12 Wash Station 01:00 13 Bluing Agent 01:00 14 Wash Station 01:00 15 Alcohol 95% 01:00 16 Eosin 00:45 17 Alcohol 95% 01:00 18 Alcohol 100% 01:00 19 Alcohol 100% 01:00 20 Xylene 01:00 21 Xylene 01:00 22 E Xylene ---- 2. Record review on 07/01/2025 of laboratory's established "H&E Staining Sakura Prisma-G2 Combo" procedure manual H&E For DIF (IFU) protocol revealed the following for Steps 2 through 18: Step Solution Time (min:sec) 2 Wash 00:45 3 Hem 02:30 4 Wash 01:00 5 acid alc 00:30 6 Wash 00:45 7 bluing 00:30 8 wash 00:45 9 95% 00:30 10 Eosin 00:40 11 95% 00:30 12 100% 00:30 13 100% 00:30 14 100% 00:30 15 XYL 00:40 16 XYL 00:40 17 XYL 00:40 18 End Xyl ---- Note: There are discrepancies with the number of steps, type of solution, and time for the staining of the slides in the staining IFU program. 3. Staff interview on 07/01/2025 at 11:55 AM with the Assistant Director (AD) confirmed the above discrepancies. The AD further commented that he/she failed to update the procedure manual when the new "IFU#1" program was place in use on the stainer. 4. The</p>

laboratory performs 2508 Immunofluorescence antibody tests annually in the subspecialty of Dermatopathology.