

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D1029962	(X3) Date Survey Completed 06/04/2026
Name of Provider or Supplier Yale University School Of Medicine	Street Address, City, State 310 Cedar St, Fmb 225, 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
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation, record review and staff interview, the laboratory failed to ensure laboratory's chemical reagents did not exceed the expiration date defined by the manufacturer in the subspecialty of histopathology. Findings include: 1. Surveyor observation on 06/04/2026 at 10:15 AM of the histopathology laboratory storage cabinets revealed the following expired chemical reagents in use: a. 1 of 1 'Sodium Phosphate, Dibasic Anhydrous', batch number: 22F1061050, expiration date: 11/18/2023. b. 1 of 1 'Buffer Solution, pH 4.00', lot number: BO003144, expiration date: 08/01/2024. c. 1 of 1 'Buffer Solution, pH 7.00', lot number: BO002856, expiration date: 06/23/2024. 2. Record review on 06/04/2026 of the laboratory's standard operating procedure revealed the lack of documentation of policies and procedures addressing the discontinuation of expired reagents and other consumables required for laboratory testing. 3. Staff interview on 06/04/2026 at 10:20 AM with the histopathology laboratory testing personnel #1 confirmed the above findings. 4. The laboratory performs 150 tests annually in the subspecialty of histopathology.</p>