

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  44D2020576	<b>(X3) Date Survey Completed</b>  07/30/2025
<b>Name of Provider or Supplier</b>  Galen East Laboratory	<b>Street Address, City, State</b>  1651 Gunbarrel Rd, Suite 102-A, Chattanooga, TN	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5417</b>	<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 observation of the laboratory and staff interviews, the laboratory failed to ensure that it did not use nine of nine lots of tissue marking dyes beyond their expiration dates in histopathology patient testing in 2024 and 2025. The findings include: 1. Observation of the laboratory on 07/30/2025 at 09:20 a.m. revealed two grossing stations used for gross examination of tissue specimens. Both stations contained marking dyes used for marking tissue. The following dyes had expired: Grossing station 1: Color Lot No Exp Date Orange 22349 12.31.24 Green 23062 03.31.25 Yellow Illegible Illegible Red 22203 10.21.24 Grossing station 2: Color Lot No Exp Date Green 22322 11.30.24 Red 22306 11.30.24 Yellow 22308 11.30.24 Orange 22214 08.31.24 Violet 22276 10.31.24 The histology technician discarded the dyes on the day of the survey. 3. An interview with the histology technician on 07/30/2025 at 9:20 a.m. confirmed that the laboratory used the observed tissue marking dyes for patient testing after expiration. .</p>