

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D2065321	(X3) Date Survey Completed 03/05/2026
Name of Provider or Supplier Connecticut Gi Laboratory, Pc	Street Address, City, State 105 Wawecus St, Ste 3, Norwich, 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
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation, record review and staff interview the laboratory failed to maintain an updated tissue processing procedure manual in the subspecialty of Histopathology. Findings include: 1. Surveyor observation on 03/05/2026 at 09:20 AM of the laboratory's work area revealed two of two "Leica Peloris III" tissue processors, Serial Number: "45111087 and 45111086" are in use. 2. Surveyor observation on 03/05/2026 at 11:48 AM of the two of two tissue processors listed in 1 above revealed three different tissue processing protocols, "Processor 1:1 hour Routine", "Processor 1:4 hour Routine" and "Processor 1:8 hour Routine" are in use. 3. Record review on 03/05/2026 of the two tissue processor's revealed 13 steps each labeled with "Type of reagent", "Processing time" and "Drop time" for three of three tissue processors listed in 2 above. 4. Record review on 03/05/2026 of the laboratory's established "Tissue Processor Operation-Sakura" standard operating procedure (SOP) revealed discrepancies in the documented "processing time" for all the 13 of 13 steps in the three protocols listed in 2 above. 5. Staff interview on 03/05/2026 at 11:48 AM with the Laboratory Supervisor (LS) confirmed the above findings. The LS further stated that the protocol on the tissue processors was correct; however, the error occurred because the "drop time" was transcribed instead of the "Processing time" in the SOP." 6. The laboratory performs 280,000 tests annually in the subspecialty of Histopathology.</p>