Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D0710066	09/04/2024
Name of Provider or Supplier	**Street Address, City, State**	
Middlesex Gastroenterology Associates, Llc	410 Saybrook Rd Ste 202, Middletown, 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
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to follow its established policy to ensure positive patient identification from the time of collection through final report in the subspecialty of Histopathology. Findings Include: 1) Record review on 9/4/2024 of the monthly incident reports from 2022 to 2024 revealed 5 of 5 specimen identification and mislabeling incidents. 2) Record review on 9/4/2024 of the laboratory's "Section 6. Quality Assurance" procedure manual revealed the laboratory failed to follow "6.2.2B Specimen Identification and Integrity" procedure. 3) Staff interview with the Laboratory Director on 9/5/2024 at 11:30AM confirmed the above findings. He/She further confirmed that the incidents listed in 1 above were identified prior to reporting of results. 4) The laboratory performs 20,484 tests annually in the subspecialty of Histopathology.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by:

	Based on record review and staff interview the laboratory failed to follow the established procedure to monitor and correct problems and when identified in the specimen handling including identification and labeling of the cassettes in the subspecialty of Histopathology. Findings Include: 1. Record review on 9/4/2024 of the laboratory's "Quality Assurance (QA) Binder" revealed total of 5 incident reports documented from 2022 to 2024. 2. Record review on 9/4/2024 of the laboratory's "Incident report, Performance Standards Failure" for the QA in 1 above revealed the below documentation for the following dates: a. 12/30/2022- "Labels swapped during accessioning and not caught during grossing" b. 01/12/2023- "Cassettes swapped at grossing." c. 01/20/2023- "not checking labels at accessioning" d. 07/06/2023- "put the wrong tissue on the slide" e. 04/15/2024- "Patient A tissue got put in a cassette labeled Patient B." 3. Record review on 9/4/2024 of the laboratory's "Incident report" for the QA in 2 above revealed the "Action Plan" for the grosser's to go slow, double check the cassettes, coaching the staff to double check and continue to retrain. 4. Record review on 9/4/2024 of the laboratory's "Quality Assurance Procedure" Section 6.1 General QA Plan revealed the following: a. "F. Actions to Resolve problem: Actions will be taken to resolve problems or improve care. Actions may include in-services, memos to staff, changes in policies and procedure, discussion of issues, acknowledgement e-mails, and/or one-on-one conferences with staff members." b. "G. Assess Actions and Document Improvement: Actions will be assessed for effectiveness. When a problem is resolved or care is improved as demonstrated through statistical data, the resolution or improvement will be documented in the MQAR." 5. Record review on 9/4/2024 of the laboratory's "Quality Assurance Binder", revealed lack of documentation of any corrective actions and its effectiveness to resolve problem and document improvement as stated in 4a and 4b above. 6. Staff interview on 9/4/2024 at 11:20 AM with the Laboratory Director confirmed the above findings. 7. This laboratory performs 20484 tests annually in the subspecialty of Histopathology.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on record review, surveyor observation, and staff interview the laboratory

	failed to provide a procedure for the proper use of tampers during the embedding process in the subspecialty of Histopathology. Findings Include: 1. Record review on 9 /5/2024 of the laboratory's General Histology Procedure Section 3.1: Grossing of GI Specimens and General Histology Procedure Section 3.5: Embedding revealed lack of documentation on how to utilize tampers in the analytical process to avoid cross-contamination. 2. Surveyor observation on 9/5/2024 at 11:15 AM revealed that twelve tampers were present in the laboratory next to the sample processing hood. 3. Staff interview with Testing Personel 1 on 9/5/2024 at 11:15AM confirmed that he/she was using tamper. He/she further stated lack of a procedure for the use of tampers in the histology laboratory. 4. The laboratory performs 20,484 tests annually in the subspecialty of Histopathology.