Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0941384	04/27/2021
Name of Provider or Supplier	**Street Address, City, State**	
G I Medicine Associates Pc	28963 Little Mack Avenue Suite 101, Saint Clair Shores, MI	

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
D3001	FACILITIES CFR(s): 493.1101(a)(1) The laboratory must be constructed, arranged, and maintained to ensure the space, ventilation, and utilities necessary for conducting all phases of the testing process. This STANDARD is not met as evidenced by: . Based on observation and interview with Testing Personnel (TP) #1 and #2, the laboratory failed to ensure that there was adequate space for conducting all phases of testing for 2 (April 2019 to April 2021) of 2 years of testing. Findings include: 1. During the tour of the laboratory on 4/27/2021 at 8:07 am, the surveyor observed during entering the laboratory that TP2 working on the Tissue-Tek embedding instrument needed to stop working to inch forward to allow us entry into the room. 2. A interview on 4/27/2021 at 8:07 am, TP2 and TP3 confirmed the laboratory was a bit tight for 2 or 3 people to work in.
D3027	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(1) Test requisitions and authorizations. Retain records of test requisitions and test authorizations, including the patient's chart or medical record if used as the test requisition or authorization, for at least 2 years. This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel (TP) #1, the laboratory failed to retain the authorization requisition for the processing of the histopathology biopsy specimens for 12 (#1 - #12) of 12 patient charts reviewed. Findings include: 1. A record review for 12 (#1 - #12) of 12 patient charts reviewed revealed the

	laboratory failed to retain on-site the authorization requisition for the processing of the histopathology biopsy testing. 2. On 4/27/2021 at 10:45 am, the laboratory was given to the end of the survey to supply the necessary documents and the documents were not received. 3. A interview on 4/27/2021 at 11:07 am, TP1 confirmed the authorization requisitions for the histopathology tissue processing are not kept on-site and was not available on the day of the survey.
D5803	TEST REPORT CFR(s): 493.1291(b) Test report information maintained as part of the patient's chart or medical record must be readily available to the laboratory and to CMS or a CMS agent upon request. This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel (TP) #1, the laboratory failed to include the name and address of the laboratory performing the histopathology tissue grossing description for 1 (#6) of 12 patient charts reviewed. Findings include: 1. A record review for 1 (#6) of 12 patient charts reviewed revealed the name and address of the processing site performing the gross description of the histopathology tissue testing was not included in the final report in the patient's electronic medical record. 2. An interview on 4/27/2021 at 10:29 am, TP1 confirmed the final report for patient #6 did not contain the name and address of the processing site for the gross description.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel (TP) #1, the laboratory director failed to ensure the final proficiency testing reports were reviewed for 2 (Event B 2020 and 2021) of 3 events reviewed. Findings include: 1. A record review of the College of American Pathologists proficiency testing records revealed the laboratory director did not review the final reports for the following events: a. HQBX1-B 2019 b. HQBX1-B 2020 2. An interview on 4/27/2021 at 10:47 am, TP1 confirmed there was no documented review of the final proficiency testing reports by the laboratory director.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

	This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel (TP) #1, the Technical Supervisor failed to assess employee competency for 1 (TP1) of 2 TP performing the highly complex histopathology tissue processing and grossing for 2 years. Findings include: 1. A review of the laboratory's competency records revealed a lack of documentation of competency assessments for TP1 for 2019 and 2020. 2. A review of the laboratory's "Policies and Procedures" manual in the "Histopathology Overview" section, the "Non-Pathologist Training and Competency Testing" for grossing will be completed at 6 months and annually thereafter. 3. An interview on 4/27/2021 at 9:28 am, TP1 confirmed competency assessments were not documented for TP1.