Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2284987	02/21/2024
Name of Provider or Supplier	**Street Address, City, State**	
Comprehensive Gi Solutions Pllc	29995 W 12 Mile Road Suite 347, Farmington Hills, 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
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: . Based on observation, record review, and interviews, the laboratory failed to establish safety procedures to ensure safety from the chemical hazard, xylene for 7 (July 2023 to February 2024) of 7 months since the laboratory began testing. Findings include: 1. An interview with the Laboratory Director on 2/21/24 at 9:02 am revealed the laboratory started its histopathology testing 7/6/23. 2. The surveyor observed a flammable cabinet on 2/21/24 at 9:21 am during a tour of the laboratory. The cabinet contained used xylene containers inside and smelled strongly of the chemical. 3. An interview on 2/21/24 at 9:30 am with Testing Personnel #1 revealed testing personnel open this cabinet daily. 4. A review of the laboratory's "Laboratory Safety" policy revealed a lack of xylene handling procedure. 5. An interview on 2/21/24 at 11:04 am with the Laboratory Director confirmed the laboratory had not established safety procedures to ensure protection from the chemical hazard, xylene.
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 a lack of records and interview with the Laboratory Director and Testing Personnel #1, the laboratory failed to retain test requisitions for its histopathology testing for at least two years for 7 (July 2023 to February 2024) of 7 months since the laboratory started testing. Findings include: 1. The surveyor requested a selection of test requests from the laboratory between July 2023 and February 2024 on 2/21/24 at 10:12 am and they were not made available. 2. An interview on 2/21/24 at 10:12 am with the Laboratory Director and Testing Personnel #1 revealed the laboratory did not routinely retain test requests.
D3041	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(6) Test reports. Retain or be able to retrieve a copy of the original report (including final, preliminary, and corrected reports) at least 2 years after the date of reporting. (i) In addition, retain immunohematology reports as specified in 21 CFR 606.160(d) (ii) and pathology test reports for at least 10 years after the date of reporting. This STANDARD is not met as evidenced by: . Based on a lack of records and interview with the Laboratory Director and Testing Personnel #1, the laboratory failed to retain test reports for its histopathology testing for at least 10 years for 7 (July 2023 to February 2024) of 7 months since the laboratory started testing. Findings include: 1. The surveyor requested a selection of test reports from the laboratory between July 2023 and February 2024 on 2/21/24 at 10:12 am and they were not made available. 2. An interview on 2/21/24 at 10:12 am with the Laboratory Director and Testing Personnel #1 revealed the laboratory did not routinely retain test reports.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: . Based on record review and interview with the Laboratory Director, the laboratory failed to include the laboratory name, address, specimen source, and test report date on histopathology test reports for 7 (July 2023 to February 2024) of 7 months since testing began. Findings include: 1. An interview with the Laboratory Director on 2/21 /24 at 9:02 am revealed the laboratory started its histopathology testing 7/6/23. 2. A review of an example of the laboratory's test report from a colonoscopy case dated 2 /12/24 on the test request revealed a lack of laboratory name, address, specimen source for each of the four specimen sites, and test report date. 3. An interview on 2/21 /24 at 10:29 am with the Laboratory Director confirmed the laboratory's test report lacked the laboratory name, address, specimen source, and test report date.

D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: . Based on record review and interview, the Laboratory Director failed to ensure testing personnel received the appropriate training and demonstrated the ability to report accurate results for 1 (Testing Personnel #2) of 2 testing personnel listed on Form CMS-209. Findings include: 1. A review of the laboratory's records revealed Testing Personnel #2, starting testing in January 2024, lacked documented training or competency assessments. 2. An interview on 2/21/24 at 10:30 am with Testing Personnel #2 revealed they had been performing specimen gross examinations independently. 3. An interview on 2/21/24 at 10:30 am with the Laboratory Director confirmed the laboratory did not perform and document training to ensure Testing Personnel #2 could perform all testing reliably and report accurate results.