Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0864536	11/19/2024
Name of Provider or Supplier	**Street Address, City, State**	
Island View Gastroenterology Associates	168 N Brent St Ste 404, Ventura, CA	

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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of policies and procedures manuals and interview with the Histology Technician (HT) on November 19, 2024, the laboratory failed to establish and follow written policies and procedures to assess testing personnel competency. The findings include: 1. It was the practice of the laboratory to perform histopathology testing. The Histology Technician was responsible for performing grossing and preparing slides for histological analysis. 2. The laboratory's HT affirmed on November 19, 2024, at approximately 9:00 am, that the laboratory did not have written policies and procedures for assessment of employee competency and maintained no documentation for competency assessment for 1 of 1 HT. 3. The laboratory's testing declaration form, signed by the laboratory director on October 9, 2024, stated that the laboratory performed approximately 6906 histopathology tests annually.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by:

	Based on interview with Histology Technician (HT) and review of Quality Assurance (QA) peer review records on November 19, 2024, it was determined that the laboratory failed to establish and follow written policies and procedures to access and correct disagreements in diagnostic evaluations identified by peer review. 1. It was the practice of the laboratory to select patients testing records monthly for the peer review to ensure that the laboratory's analytic systems protocols were being followed and met. The review of the QA peer review for 2024 showed that there were disagreements in diagnostic evaluation for case #v24-1004, and no corrective action was taken to address or resolve the disagreement. 2. On November 19, 2024, at approximately 9:00 am, the laboratory HT affirmed the laboratory maintained no written protocols for assessing and correcting the diagnostic disagreements. 3. The laboratory's testing declaration form, signed by the laboratory director on October 9, 2024, stated that the laboratory performed approximately 6906 histopathology tests annually.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. This STANDARD is not met as evidenced by: Based on review of laboratory's policies and procedures manuals, Competency evaluation, Quality Assurance (QA) records, review of 6 randomly selected patient test results and interview with Histology Technician (HT) on November 19, 2024, it was determined that the Laboratory director of high complexity testing failed to ensure that testing systems developed and used for histopathology procedure provide quality laboratory services for all aspects of test performance. See D5209, D5791.