Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2161289	02/17/2022
Name of Provider or Supplier	**Street Address, City, State**	
San Diego Digestive Disease Consultants	8008 Frost St Ste 200, San Diego, 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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory's evaluation of proficiency testing performance (EPTP) records, and interview with the laboratory testing personnel, it was determined that the laboratory failed to verify the accuracy, at least twice annually, of histopathology it performed, that is not included in subpart I of 42 CFR part 493. The findings included: a. The laboratory performed histopathology testing which is not listed/included in subpart I of 42 CFR part 493. b. The laboratory failed to perform EPTP to verify and ensure the accuracy, reliability and timely of the patient test result reports, at least twice annually. c. Review a copy of "Slide Proficiency Testing Evaluation Form Summary" under "1st Event - June ____ 2020" by "Bradly Clark, MD - Laboratory Director, A list of 5 patient testing slides including TGE -20-000112, TGE - 20-000134, TGE -20-000121, TGE -20-000321, and TGE -20-000336., NO evidences of the "Reviewing MD Name and Signature" to indicate the review in the year of 2020. d. The laboratory Quality Assurance (QA) and Assessment Plan indicates "QUALITY ASSURANCE ACTIVITIES & PROCEDURE: under "Proficiency Testing" - "Peer Performance Review are performed twice a year, a total of 10 cases per year," e. The laboratory failed to follow and perform its established and written policy and procedure (P&P) of "Proficiency Testing" requirement (d) aboce. f. Peer review of the patient test result reports of TGE-20-000856 and TGE -20-000857, both dated of service (DOS) on 10/30/2020, and had indicated a peer reviewed with the consent diagnosis by a qualified pathologist and signed on 2/16 /2022 to provide the evidences of CLIA requirement of EPTP, for the year of 2020. g. Peer review of the patient test result reports,TGE-21-000103 and TGE -21-000447, DOS on 2/18/2021 and 6/30/2021, respectively, and had indicated a peer reviewed

	with the consent diagnosis by a qualified pathologist and signed on 1/31/2022 to provide the evidences of CLIA requirement of EPTP, for the year of 2021. i. The laboratory failed to follow its QA P&P, twice a year, to verify and to ensure the accuracy, reliability, and timely of the patient test result reports, and failed to perform consistently procedures with its established and written P&P, j. The laboratory performed histopathology in approximately 220 patient samples each month. k. The laboratory personnel affirmed (2/17/2022 @ 11 AM) that the laboratory failed to follow its P&P for EPTP twice a year to verify and to ensure accuracy, reliability, and timely of the patient test result reports.
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 review of the laboratory's evaluation of proficiency testing performance (EPTP) records, and interview with the laboratory testing personnel, it was determined that the laboratory failed to follow written policies and procedures (P&P) for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems. The findings included: a. The laboratory performed histopathology testing which is not listed/included in subpart I of 42 CFR part 493. b. To ensure and verify the accuracy of histopathology testing result reports, the laboratory elected to perform EPTP by peer review procedure twice a year. c. The laboratory failed to follow its written P&P to perform EPTP to verify and to ensure accuracy, reliability and timely of the patient test result reports, twice a year, see D-5217.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the laboratory's evaluation of proficiency testing performance (EPTP) records, and interview with the laboratory testing personnel, it was determined that the laboratory director failed to ensure that the quality control programs were established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. The findings included: a. The laboratory performed histopathology testing which is not listed/included in subpart I of 42 CFR part 493. b. The laboratory elected to perform EPTP by a qualified testing person to review the cases for twice a year to verify and to ensure accuracy, reliability, timely of the patient test result reports. c. The laboratory director failed to ensure that the quality control programs were maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur., see D-5791

D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the laboratory's evaluation of proficiency testing performance (EPTP) records, and interview with the laboratory testing personnel, it was determined that the laboratory director failed to ensure that the quality assessment programs were established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. The findings included: a. The laboratory performed histopathology testing which is not listed/included in subpart I of 42 CFR part 493. b. The laboratory elected to perform EPTP by a qualified testing personnel to review the cases twice a year. c. The laboratory director failed to ensure that the quality assessment programs were established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.
D6095	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6) The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system. This STANDARD is not met as evidenced by: Based on review of the laboratory's evaluation of proficiency testing performance (EPTP) records, and interview with the laboratory testing personnel, it was determined that the laboratory director failed to ensure the establishment and maintenance of acceptable levels of analytical performance for each test system. The findings included: a. The laboratory performed histopathology testing which is not listed/included in subpart I of 42 CFR part 493. b. The laboratory director failed to ensure the establishment and maintenance of acceptable levels of analytical performance for histopathology test system, see D-5217