

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D1018160	(X3) Date Survey Completed 08/26/2026
Name of Provider or Supplier Digestive Disease Associates, Inc	Street Address, City, State 292 Euclid Ave, Ste 115, 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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. In addition, retain the following: This STANDARD is not met as evidenced by: Based on observation of the histology laboratory for receiving and grossing gastroenterology tissue biopsies, review of laboratory records, the lack of records, and interview with Testing Person-2, it was determined the laboratory failed to retain original Gross descriptions records for at least two years. Findings included: a. The gastroenterology practice equipped the laboratory to receive GI biopsies from the surgery center and perform Gross descriptions. b. Laboratory Personnel reports (CMS 209 and LAB116, 8/26/26) named four Testing persons performing and reporting Gross Description results for the laboratory reports. c. For 4 out of 5 laboratory pathology reports selected from 2024 for this survey, the laboratory failed to have the original Grossing Log document used by the Testing Personnel to record the specimen Accession number, first and last name, specimen source, number of pieces, and Size and Color; as follows: Date received Accession # Grossing Log ----- 8/07/24 DS24-03294 No 8/12/24 DS24-03348 No 8/20/24 DS24-03491 No 8/22/24 DS24-03531 No 12/30/24 DS24-05451 Yes d. Testing Person-2 affirmed (8/26/26 at 3:30 PM) the aforementioned findings and that the Grossing Log documents had been discarded before reaching two years. And thus, the laboratory failed to retain analytic records for at least two years as required by CLIA, and for three years as required by California Business & Professions Code (BPC) section 1265(j)(2)(A). 1. BPC 1265(j)(2)(A): Notwithstanding any other provision of law, owners and laboratory directors of all clinical laboratories, including those laboratories that cease operations, shall preserve

medical records and laboratory records, as defined in this section, for three years from the date of testing, examination, or purchase, unless a longer retention period is required pursuant to any other provision of law, and shall maintain an ability to provide those records when requested by the department or any duly authorized representative of the department . .