

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0270615	(X3) Date Survey Completed 10/28/2021
Name of Provider or Supplier Digestive Diseases Center	Street Address, City, State 204 E 19th St, Panama City, FL	
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
D0000	A CLIA recertification survey was conducted on October 28, 2021. Digestive Diseases Center clinical laboratory was not in compliance with 42 CFR 493, Requirements for Clinical Laboratories.
D5293	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c)</p> <p>(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with Testing Personnel (TP) #A, the laboratory failed to show documentation for "Quality Assessment Review" activity for the timeframe of July 2019 to October 2021. Findings included: Record review of the laboratory's Quality Assurance Plan revealed no documentation of "Quality Assessment Review" activity from July 2019 to October of 2021. During interview on 10/28/2021 at 1200 with TP #A, it was confirmed there was no "Quality Assessment Review" being performed.</p>