

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D0521878	(X3) Date Survey Completed 07/25/2022
Name of Provider or Supplier Digestive Health Clinic Llc	Street Address, City, State 6259 W Emerald St, Boise, ID	
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
D5475	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(3)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (3) Check fluorescent and immunohistochemical stains for positive and negative reactivity each time of use. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on a review of laboratory quality control (QC) documents and an interview with the laboratory director (LD) on 7/25/2022, the laboratory failed to have documentation of daily Hematoxylin and Eosin (H&E) QC for November 2021. The findings include: 1. A review of H&E daily QC logs identified that the laboratory failed to have daily QC documentation of H&E stains for the month of November 2021. 2. An interview with the LD on 7/25/2022 at 1:40 pm confirmed that the laboratory failed to have documentation of H&E stain QC for November 2021. 3. The laboratory performed H&E stains 20 days in November 2021 on 704 patient cases.</p>