

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2063353	(X3) Date Survey Completed 08/24/2022
Name of Provider or Supplier B Jeffrey Wallis Md Pa D/B/A	Street Address, City, State 6208 W Corporate Oaks Dr 2nd Fl, Crystal River, 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	An unannounced complaint survey, #2022011610, was conducted on 08/24/2022 at B. Jeffery Wallis MD PA DBA Advanced Gastroenterology. The laboratory was not in compliance with 42 CFR 493, Requirements for Laboratories.
D3001	<p>FACILITIES CFR(s): 493.1101(a)(1)</p> <p>The laboratory must be constructed, arranged, and maintained to ensure the space, ventilation, and utilities necessary for conducting all phases of the testing process.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the Office Manager the laboratory failed to monitor Formaldehyde and Xylene exposure limits for 2 out of 2 years (2020-2022) reviewed. Findings Included: Review of the "Safety Manual and Records" signed by the Laboratory Director on 11/02/2021 revealed Formaldehyde and Xylene exposure monitoring was to be conducted on an annual basis. Documentation review revealed no evidence to demonstrate the exposure monitoring had been performed for 2020 through the date of survey (8/24/22). On 08/24/2022 at 5:00 PM, the Office Manager confirmed there was no documentation of exposure monitoring.</p>
D3011	<p>FACILITIES CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review, and interview with the Office Manager the</p>

laboratory failed to store liquid chemical waste in a flammable cabinet and failed to store Eosin in a flammable cabinet. Findings Included: A tour of the laboratory on 08/24/2022 at 4:00 PM revealed 1 container of 5 gallons of liquid chemical waste that contained xylene and 3 containers of 1 gallon (each) of liquid chemical waste that contained 100% reagent alcohol and Eosin. Continued observations also revealed a 1 gallon container of Eosin stored on a shelf above the manual stainer. Review of the laboratory's "Chemical Hygiene Plan" last signed by the Laboratory Director on 11/02/2021 revealed "Waste disposal will be conducted in accordance with EPA [Environmental Protection Agency] standards. Xylene will be stored in the flammable cabinet until removed by a licensed facility." Review of the SDS (safety data sheet) for Eosin revealed "Store tightly closed in an approved flammable liquid storage area." Review of the SDS for 100% Reagent alcohol revealed "Store in an approved Flammable Liquids storage area." On 08/24/2022 at 4:00 PM, the Office Manager confirmed the Eosin and the chemical waste were not stored in a flammable cabinet.