

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D2293615	<b>(X3) Date Survey Completed</b>  03/12/2025
<b>Name of Provider or Supplier</b>  Stuart Oncology Associates Pa	<b>Street Address, City, State</b>  11250 Sw Village Parkway, Ste C, Port Saint Lucie, FL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An onsite complaint survey #2025002837 was conducted at Stuart Oncology Associates PA on March 12, 2025. The laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories.
<b>D3011</b>	<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, review of the procedure manual, and interview, the laboratory failed to follow their safety procedure to ensure protection from biohazardous materials from 03/06/2025 to 03/12/2025. Findings: During a tour of the laboratory on 03-12-2025 at 10:10 AM, the refrigerator/freezer was observed in the break room containing laboratory reagents and patient samples. The refrigerator contained Horiba ABX Minotrol 16 Controls (Level 1,2, 3), Horiba ABX Minocal Whole Blood Calibrator, American Proficiency Institute 2025 Hematology/Coagulation 1st event samples, two frozen patient serum, and one patient serum sample in the refrigerator. There were three bottles of water, one bottle of soda, coffee grinder, coffee maker, coffee beans, coffee syrup, and a microwave on the counter. There were condiments, silverware, and an open case of bottled water noted in the cabinet. Review of the Horiba ABX Minotrol 16 Controls (Level 1,2, 3) and the Horiba ABX Minocal Whole Blood Calibrator package inserts read, "The whole blood reagent may contain any of the following: stabilized human red blood cells, a white blood cell component consisting of human and/or non-human analogs and a platelet component consisting of a human or non-human analog in a preserved media. The package insert also stated "Caution: All blood products should be treated as potentially Infectious." Review of</p>

the procedure titled, General Laboratory Safety Program, read ""Food and drink may not be stored in the laboratory, near any specimens, or in and area where bio hazardous material are stored. (such as the laboratory refrigerator)." During an interview on 03/12/2025 at 11:00 AM, the Technical Consultant confirmed they ate in the break room were laboratory reagents and patient samples were stored in the laboratory refrigerator/freezer.