

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D2124376	<b>(X3) Date Survey Completed</b>  01/27/2023
<b>Name of Provider or Supplier</b>  Sea Level Labs Llc	<b>Street Address, City, State</b>  3134 Gulf Breeze Pkwy, Gulf Breeze, 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 unannounced complaint survey, #2022017829, was conducted on January 13, 2023 at Sea Level Labs, LLC. The facility was not in compliance with 42 CFR 493, Requirement for clinical laboratories.
<b>D3011</b>	<p><b>FACILITIES</b> 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 direct observation and interview with laboratory manager and Testing Personnel (TP #A), the laboratory failed to keep food and drink materials separate from the Polymerase Chain Reaction (PCR) testing environment. Findings include: Observation of the laboratory refrigerator on 1/13/2023 at approximately 7:00 pm, revealed a pint of milk and a bottle of Dasani drinking water inside the patient sample /reagent refrigerator. Observation of the laboratory desk area on 1/13/2023 at approximately 7:10 pm, that is within 5 -6 feet from the PCR testing environment, revealed a used coffee cup, a closed lunch container, and a large coffee creamer jug. Interview with laboratory manager and TP #A on 1/13/2023 at 7:40 pm, confirmed there were drinks and food containers in the laboratory.</p>