Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2260316	10/27/2022
Name of Provider or Supplier	**Street Address, City, State**	
Suncoast Labs Llc	1112 Third Street Suite 7, Neptune Beach, 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	At the time of the announced, on-site initial certification survey, Suncoast Labs Llc, was found to be NOT in compliance with the CLIA laboratory requirements of 42 CFR 493.
D5425	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(3) The laboratory must determine the test system's calibration procedures and control procedures based upon the performance specifications verified or established under paragraph (b)(1) or (b)(2) of this section. This STANDARD is not met as evidenced by: Based on record review and staff interview, the facility failed to develop a means to detect cross contamination of patient samples throughout the entire testing process since the laboratory opened in August 2022. The findings include: The record review of patient testing records showed the facility adds positive and negative control material to the amplification stage of testing, but has no control material testing from extraction through amplification. Laboratories performing molecular amplification procedures should have a mechanism to detect cross-contamination of patient specimens. This may be accomplished by including a "blank" or "No-Template Control" with each run of patient specimen testing. The interview with testing person A on 10/27/22 at 11:00am confirmed no quality control to determine cross-contamination was performed from extraction and followed through to amplification.