

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1076060	(X3) Date Survey Completed 11/28/2023
Name of Provider or Supplier Sarkis Clinical Trials	Street Address, City, State 611 C Nw 60th Street, Gainesville, 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, #2023013527, was conducted on 10/30/23 at Sarkis Clinical Trials. The facility was found not in compliance with 42 CFR 493, Requirement for clinical laboratories.
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on observation and interview, the facility failed to follow manufacturer instructions by using an expired Covid antigen testing kit on 14 patients tested in 2023. Findings include: During the tour of the laboratory, one kit of "Care Start Covid-19 Antigen" tests with lot number CH21A28 and expiration date of 11/30/21 was located. The box was opened with 6 test strips remaining out of 20. The laboratory provided a list of 14 patients who were potentially tested with the expired kit. Interview with an Access Bio (manufacturer of Care Start Covid-19 Antigen) technical services representative via telephone on 10/30/23 at 9:38am confirmed the test kit was past any extended expiration date. Interview with the Director of Clinical Trials on 10/30/23 at 9:42am confirmed the Care Start kit with expiration date of 11/30/21 is the only Covid-19 test kit on site.</p>