

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2104407	(X3) Date Survey Completed 08/12/2019
Name of Provider or Supplier Beach Care Pllc	Street Address, City, State 1000 5th Street Suite 200-Ys, Miami 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	An initial certification survey conducted at Beach Care LLC; on 8/12/2019 found that the laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories.
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with Technical Consultant (TC), it was found that the instrument verification for Istat and Abaxis Piccolo analyzers was incomplete. Findings include: Record review of performance verification revealed that: - For Istat analyzer, for Cardiac markers, there was no documentation of the accuracy and precision evaluation. - For Abaxis Piccolo analyzer performance, for Comprehensive Metabolic Panel, there was no documentation of the accuracy and precision evaluation. During an interview on 8/12/19 at 11:30 AM, the TC acknowledged that there was no validation for the equipment of above-reference.</p>